UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION THIS DOCUMENT RELATES TO: *Saint Elizabeth Medical Center, Inc. d/b/a St. Elizabeth Healthcare v. AmerisourceBergen Drug Corp., et al.*; Case No. 18-op-46046	**MDL No. 2804** **Case No. 17-md-2804** **SECOND AMENDED COMPLAINT** **Judge Dan Aaron Polster**

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COMPLAINT

Plaintiff Saint Elizabeth Medical Center, Inc. d/b/a St. Elizabeth Healthcare brings this Complaint against Defendants Walgreen Co.; Walgreen Eastern Co., Inc.; Walgreens Boots Alliance, Inc.; CVS Health Corporation; CVS Pharmacy, Inc.; CVS Indiana L.L.C; CVS Rx Services, Inc.; CVS Orlando FL Distribution, L.L.C.; CVS TN Distribution, L.L.C.; CVS Health Solutions LLC; and Walmart Inc. f/k/a Wal-Mart Stores, Inc.; and Wal-Mart Stores East, LP (collectively "Defendants") stating as follows:

I. INTRODUCTION

1. Plaintiff operates a hospital that provides acute care, including required[1] treatment of opioid-dependent patients and patients suffering from opioid-related conditions.[2] These patients routinely seek services at Plaintiff's emergency room and occupy beds in Plaintiff's hospital. As a hospital operator, Plaintiff is legally and morally compelled to treat these patients, regardless of the cost of treatment.

2. As a direct and proximate result of Defendants' acts and omissions detailed *infra*, in the course of treating OUD-patients, Plaintiff has suffered and will continue to suffer loss, injury, damage, and special injury.

3. As detailed *infra*, Defendants engaged in a civil conspiracy (1) in their unlawful marketing, distributing, and dispensing of opioids into Kentucky and its communities, including

[1] The Emergency Medical Treatment and Labor Act (EMTALA) is a federal law that requires anyone coming to an emergency department to be stabilized and treated. Plaintiff treated opioid-dependent patients pursuant to EMTALA.

[2] "Opioid-related conditions" include but are not limited to opioid use disorder and overdose; psychiatric and mental health treatment; neonatal abstinence syndrome ("NAS") or other opioid-related conditions of newborns; illnesses associated with opioid use, such as endocarditis, hepatitis C, and HIV; medical procedures made more complex and expensive due to a patient's opioid use or dependence; illnesses or other conditions claimed by a person with opioid use disorder in order to obtain an opioid prescription; and any other condition identified in Plaintiff's records as related to opioid use, misuse, or dependence.

in the service areas and patients of Plaintiff, (2) in their fraudulent misrepresentation relating to their unlawful marketing, distribution, and dispensing of opioids, (3) in their violation of the Controlled Substances Act ("CSA"), 21 U.S.C. Sections 801, *et seq*. and (4) in their violation of the Racketeering Influenced and Corrupt Organizations Act (18 U.S.C. §§ 1961–1968) ("RICO").[3]

4. Through various professional associations and organizations, as well as through various marketing, distribution and dispensing schemes, Defendants, acted in concert to violate the CSA and deviate from their professional and legal obligations for the purpose of creating an illegitimate demand for dangerous opioids, thereby increasing their sales and profits.

5. Defendants' unlawful conduct improperly inflated the market for opioids. Defendants promoted opioids as safe and appropriate for use to treat a range of chronic conditions while downplaying their addictive and dangerous properties.

6. Defendants (a) improperly dispensed controlled substances based on prescriptions issued by physicians who were not licensed to practice medicine; (b) dispensed controlled substances to individuals with prescriptions issued for illegitimate medical purpose; (c) dispensed controlled substances to individuals that Defendants knew or should have known were diverting controlled substances; and (d) dispensed controlled substances based on prescriptions that contained expired, suspended, or invalid DEA numbers, often refilling prescriptions for controlled substances too early.

7. Factors that further contributed to Defendants' improper opioid dispensing practices include store-level procedures, management pressure, distribution center activities, and

[3] As is detailed in the Counts *infra*, Plaintiff is litigating its causes of action for Civil Conspiracy (other than RICO) and Nuisance in the bellwether action for Plaintiff in *In re: National Prescription Opioid Litigation*, Case No. 1:17-md-02804-DAP, Track 23. Plaintiff's claims against Defendants for RICO are severed from said bellwether action and are stayed. Defendants are not required to answer the RICO allegations in said bellwether action.

pharmaceutical company sponsorship.[4] Through these actions, Defendants flooded communities across the country, including those in Plaintiff's service area, with unreasonable and unjustifiable quantities of opioids.

8. Defendants conspired and cooperated to sell, ship, and dispense ever-increasing quantities of opioids as part of a racketeering enterprise—the Opioid Promotion Enterprise. Defendants' acts and omissions were purely for their monetary gain; they were, in essence, a cartel reaping multi-billion-dollar profits in connection with their scheme.

9. The origins of the current crisis began in the 1990s when Purdue released OxyContin. To ensure that OxyContin was profitable, it needed wide adoption by the medical community which was leery. As such, Purdue orchestrated an extensive lobbying and marketing campaign in which Defendants partook to significantly expand approved uses for opioids while minimizing and misrepresenting the dangerous and addictive nature of opioids, all for the purpose of increased profits.

10. Defendants and their co-conspirators—through formal and informal agreements, and/or through front groups, and organizations—propagated falsehoods about the safety and benefits of opioids and the manner in which they are or should be distributed and dispensed, and Defendants knowingly and purposefully distributed and dispensed opioids in violation of the Controlled Substances Act.

11. Defendants, through their conspiracy and unlawful acts complained of herein, worked for their mutual financial benefit, each profiting from a perversely enlarged market for the

[4] Chiu C., Wong, A., Chen, J., Roderos A., Apollonio, D., Retail chain pharmacy opioid dispensing practices from 1997 to 2020: A content analysis of internal industry documents, Drug and Alcohol Dependence Reports, Vol. 9, 2023, 100199 (https://doi.org/10.1016/j.dadr.2023.100199).

addictive opioid prescriptions. Opioid sales—less than $1 billion in 1992—ballooned to $8 billion in 2015.

12. In furtherance of their common unlawful goal, Defendants engaged in a concerted campaign to convince regulators to raise the DEA's quotas for these controlled substances to unprecedented heights, enabling Defendants to sell, distribute, and dispense more and more opioids. Defendants' internal policies supported unbridled distribution and dispensing of the controlled substances. Each Defendant distributed and dispensed opioids, while avoiding their obligations to detect and refuse suspicious orders, which is necessary to prevent controlled substances from being diverted out of legitimate channels.

13. Specifically, Defendants failed to design and implement systems to (a) prevent diversion of controlled substances, and (b) monitor and report suspicious activities in their retail pharmacy operations. Defendants collaborated with their distributors and customers by devising ways to avoid triggering a review of orders as suspicious, and failed to halt shipment of potentially suspicious orders until the suspicion was dispelled.

14. Further, as retail pharmacies, Defendants had a duty to analyze data and store-level information for red flags such as (a) multiple prescriptions to the same patient using the same doctor; (b) multiple prescriptions by the same patient using different doctors; (c) prescriptions of unusual size and frequency for the same patient; (d) prescriptions of unusual size and frequency from out-of-state patients; (e) an unusual or disproportionate number of prescriptions paid for in cash; (f) prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g) prescriptions in volumes, doses, or combinations that suggested the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) prescriptions for patients and doctors in combinations that were

indicative of diversion and abuse. Defendants failed in the discharge of their duties owed, causing Plaintiff to suffer increased operational losses as a result of encounters with OUD-patients, including encounters pursuant to EMTALA.

15. Defendants' conduct constituted repeated, related, and continuous acts of mail fraud, wire fraud, corruption of official proceedings, and violations of the Controlled Substances Act and its state law analogs, including but not limited to KRS 218A.180(4); 902 KAR 55:080; 902 KAR 55:105 § 3; KRS 218A.180(5); KRS 218A.180; 201 KAR 2:100; KRS 315.335; KRS 315.121. As these acts were committed to further the purpose of the Opioid Promotion Enterprise, they give rise to liability under the Racketeer Influenced and Corrupt Organizations Act.

16. By misleading doctors and patients regarding the safety and efficacy of prescription opioids, by failing to take the steps required by law to prevent the diversion of controlled substances, and by misleading authorities regarding all of this conduct, the Opioid Promotion Enterprise caused a flood of opioids to be prescribed, distributed, and dispensed—in Kentucky and within the service area and location of patients of Plaintiff, resulting in operational losses to Plaintiff, including as a result of increased OUD patient encounters at Plaintiff's hospitals.

17. The opioid epidemic poses an ongoing crisis for Kentucky, and its acute care hospitals, with tragic consequences for communities across Kentucky. During the period from 2006 to 2014, approximately 3,595,806,356 prescription pain pills were supplied for distribution in Kentucky. Kentucky ranked second in the country (only after West Virginia) for states that received the highest concentrations of pills per person per year. Rural Perry County, Kentucky averaged 175 pills per person. During that same time, six companies were responsible for more than 75% of all opioids distributed: Defendants Walgreens, Walmart and CVS ranked #4, #5 and

#6, only after the "Big 3" Distributors, McKesson, Cardinal and AmerisourceBergen. Indeed, Defendants' practices made Kentucky part of the lethal "Blue Highway."

18. According to the Office of National Drug Control Policy's Opioid Overdose Tracker, the rate of nonfatal opioid overdoses in Kentucky continues to be higher than the national average.[5] Similarly, in 2021, the rate of fatal overdoses due to prescription opioids in Kentucky was 9.9 per 100,000 persons, the fifth largest rate of all fifty states.[6]

19. Overdose deaths are just one devastating consequence of opioid abuse. Addicts who are not killed by drug addiction experience a variety of health consequences (including non-fatal overdoses) and engage in a variety of risky drug-seeking behaviors. Widespread drug addiction imposes costs on the community, including the imposition of particularly harsh consequences for acute care hospitals, resulting in a myriad of losses.

20. In addition to the cost of the opioid drugs themselves, acute care hospitals, including St. Elizabeth, have incurred losses associated with staffing shortages, physical and emotional fatigue and distress stemming from the relentless cycle of encounters with opioid-use-disordered patients, increased security concerns and continue to incur damages for the economic losses associated with the treatment and care of opioid-dependent patients.

21. Because of Defendants' conduct, the opioid epidemic is placing an increasing strain on the overburdened health care system in Kentucky, including at St. Elizabeth's. Plaintiff struggles with the relentless and crushing mental, operational and financial burdens caused by the epidemic of opioid dependence.

[5] Opioid Overdose Tracker, NEMSIS, https://nemsis.org/opioid-overdose-tracker/ (last visited Sept. 12, 2023).
[6] *Id.*

22. The effects of the opioid epidemic on hospitals may worsen. The coverage rules under the Affordable Care Act ("ACA"), Medicare and Medicaid are in transition, thus creating increased losses for hospitals in relation to their treatment of opioid-dependent patients admitted under the Emergency Medical Treatment and Labor Act ("EMTALA"), 42 U.S.C. § 1395dd.

23. St. Elizabeth must nevertheless admit and treat opioid-dependent patients who present themselves in need of emergency and/or intensive care or who display symptoms of mental illness. In addition, if an opioid-dependent patient is pregnant, and presents herself for treatment, St. Elizabeth must provide care for both the opioid-dependent mother and her opioid-dependent baby. As a result of the opioid dependence epidemic, including in the area which Plaintiff serves, opioid-dependent patients routinely occupy beds in hospitals operated by Plaintiff.

24. Many of the patients treated have no insurance and do not pay for their care. However, irrespective of insurance, St. Elizabeth has been increasingly caused to treat opioid disordered patients who present to the hospital, to their own operational and financial detriment.

25. St. Elizabeth encounters patients with opioid dependence on a daily basis. Plaintiff must treat and stabilize patients who have serious medical conditions. The patient cohort that is opioid-use-disordered typically uses extra care and/or resources and require extra time, all at extra expense (in comparison to the non-OUD patient cohort) because the patient is dependent on opioids.

26. The statistics are startling. Adult hospitalizations due substantially to opioid-related medical conditions doubled from 2000 to 2012. From 2005 to 2014, emergency department visits exhibited a 99.4% cumulative increase.

27. Plaintiff suffered proximate, foreseeable, direct and resulting special injury, injury, damage, and loss from Defendants' acts and omissions. The Hospitals are not seeking

unreimbursed costs resulting from treatment of a third party. The Hospitals seek the operational losses suffered as a result of treating OUD patients (defined as a patient with a chronic pain diagnosis plus prescription). The injury is not exclusive to opioid-related diagnoses, like overdose. Instead, the evidence shows that an OUD patient often presents with more complexity, requiring more resources to treat an OUD-patient cohort in comparison to a non-OUD patient cohort for the same diagnosis code(s). The analysis is confirmed when comparing the Diagnoses Related Groups (DRGs) assigned for a diagnosis to an OUD patient vs. a non-OUD patient. Moreover, clinical testimony supports what the data reveal. For example, if a patient presents to the emergency department with symptoms eventually diagnosed as simple pneumonia and pleurisy, it will require more care and time to treat the OUD patient with pneumonia than it will for a non-OUD patient with pneumonia. When compared between the two patient cohorts (OUD and non-OUD) St. Elizabeth will uniformly suffer more losses when treating the OUD patient due to various complexities associated with ruling in/ruling out and the attendant resources utilized in doing so, than it will when treating the non-OUD patient. Further analysis of actual aggregate claims data associated with the Hospitals reveals that the difference between the two cohorts is about 8 percent in terms of operational losses. Notably, the analysis only reflects OUD patients as being those patients who have (a) a chronic pain diagnosis (Defendants promoted chronic pain as a diagnosis for which opioids should be prescribed) and (b) a prescription in their medical history. This is an aggregate, anonymized analysis of claims data, just like big companies like IQVIA and Blue Health Intelligence (BCBS's claims data bank) use all the time. Plaintiff does not allege that "overdose patients do not pay their bill, so defendants should." The OUD patients' bills get paid, they simply do not get paid at the same realization rate as non-OUD patients. Nor does the payment of a bill reflect the extra staffing needed due to compassion fatigue or security concerns.

28. Plaintiff has suffered and will continue to suffer operational losses as a result of the epidemic intensified and perpetuated by Defendants.

II. JURISDICTION AND VENUE

29. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 as Plaintiff's cause of action arises under the laws of the United States, specifically the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §§ 1961–1968 and pursuant to 28 U.S.C. § 1332 as Plaintiff is diverse from all Defendants and the value of the claim exceeds the jurisdictional amount.

30. This Court has personal jurisdiction over Defendants because at all relevant times Defendants engaged in substantial business activities in Kentucky and purposefully directed their actions towards Kentucky, voluntarily submitted to the jurisdiction of Kentucky when obtaining a manufacturer, pharmacy, and/or distributor license, and have the requisite minimum contacts with Kentucky necessary to constitutionally permit this Court to exercise jurisdiction.

31. Alternatively, this Court has personal jurisdiction over all Defendants pursuant to 18 U.S.C. § 1965(a)–(b), (d). At least one Defendant is subject to this Court's personal jurisdiction. 18 U.S.C. § 1965(a).

32. Concerning Defendants' conspiracy, the ends of justice require application of RICO's nationwide service of process provisions to any Defendants over whom this Court would otherwise lack personal jurisdiction. 18 U.S.C. § 1965(b). Defendants' racketeering conduct took place throughout the United States, including substantial conduct within Kentucky, and their conduct injured Plaintiff in the State of Kentucky. Holding Defendants to account in this district, then, is only proper. Doing so will also ensure Plaintiff will not be required to litigate its claims beyond its home district in various courts across the United States. Congress expressly provided nationwide service of process as a basis for personal jurisdiction in RICO actions. Exercising

personal jurisdiction over all Defendants in this case pursuant to RICO's nationwide service of process provisions thus serves and advances Congress's policy goals.[7]

33. Kentucky is a fair, reasonable, and not unduly inconvenient forum such that the Fifth Amendment's due process requirements are satisfied. Defendants regularly transact their affairs across the United States and very frequently did so in Kentucky; Defendants' actions have injured Plaintiff in Kentucky; the document discovery in this case will be almost exclusively electronic, rendering any geographic distance between the document repositories and this Court immaterial; Defendants have access to sophisticated legal counsel who can readily litigate in any U.S. jurisdiction; and judicial economy is best served by adjudicating Plaintiff's claims against all Defendants in a single court. Accordingly, this Court may exercise personal jurisdiction over all Defendants pursuant to RICO's nationwide service of process provisions.[8]

34. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Plaintiff was injured in this district and because Defendants marketed, sold, distributed, and/or dispensed prescription opioids in this district, as well as owned and/or maintained property, employees and agents in this district.

35. Alternatively, venue is proper in this Court pursuant to RICO's nationwide service of process provisions. 18 U.S.C. §§ 1965(a)–(b), (d).[9]

III. PARTIES

A. Plaintiff

36. Plaintiff Saint Elizabeth Medical Center, Inc. d/b/a St. Elizabeth Healthcare ("St. Elizabeth" or the singular "Plaintiff") is a Kentucky non-profit corporation, having its main

[7] *See supra* n.3, indicating Defendants are not now required to answer the specific RICO allegations of this paragraph within the bellwether, Track 23.
[8] *Id.*
[9] *Id.*

location at One Medical Village Drive in Edgewood, Kenton County, Kentucky and additional full-service hospital campuses in Boone, Campbell, and Grant County, Kentucky. St. Elizabeth is licensed for a total of 932 acute-care beds and 20 psychiatric beds serving patients in its primary service area of Kenton, Boone, Campbell, Grant, Gallatin, Owen, and Pendleton Counties in Northern Kentucky. It provides Emergency Department services at each of its four main campuses and at its standalone ED facility in Covington, Kenton County, Kentucky.[10]

B. Defendants and Unnamed Associates

1. Defendants in this Action

a. CVS

37. Defendant CVS Health Corporation is a Delaware corporation with its principal place of business in Rhode Island.

38. Defendant CVS Pharmacy, Inc. is a Rhode Island corporation with its principal place of business in Rhode Island. CVS Pharmacy, Inc. affirmatively registered with the State of Kentucky and maintains an agent in Frankfort, KY.

39. Defendant CVS Indiana L.L.C. is an Indiana limited liability company with its principal place of business in Rhode Island. CVS Indiana L.L.C. affirmatively registered with the State of Kentucky and maintains an agent in Frankfort, KY.

40. Defendant CVS Rx Services, Inc. is a New York corporation with its principal place of business in Chemung, New York. CVS Rx Services, Inc. affirmatively registered with the State of Kentucky and maintains an agent in Frankfort, KY.

[10] Also named as plaintiffs in this action are (1) St. Claire Medical Center, Inc. d/b/a St. Claire Regional Medical Center ("St. Claire") and (2) Highlands Hospital Corporation d/b/a Highlands Regional Medical Center ("Highlands"). This amended complaint is brought solely on behalf of St. Elizabeth and serves solely to amend the claims brought by St. Elizabeth, a bellwether plaintiff. The claims of St. Claire and Highlands remain pending and are governed by the previously operative complaint that they filed.

41. Defendant CVS Orlando FL Distribution, L.L.C. is a Florida limited liability company.

42. Defendant CVS TN Distribution, L.L.C. is a Tennessee limited liability company. CVS TN Distribution, L.L.C. affirmatively registered with the State of Kentucky and maintains an agent in Frankfort, KY.

43. Defendant CVS Health Solutions LLC is a Delaware limited liability company. CVS Health Solutions LLC affirmatively registered with the State of Kentucky and maintains an agent in Frankfort, KY.

44. CVS Health Corporation, CVS Pharmacy, Inc., CVS Indiana L.L.C., CVS Rx Services, Inc., CVS Orlando FL Distribution, L.L.C., CVS TN Distribution, L.L.C, and CVS Health Solutions LLC are collectively referred to as "CVS."

45. CVS distributed, dispensed, and promoted prescription opioids throughout the United States and in Kentucky. CVS has a multitude of subsidiaries and agents for whom CVS affirmatively registered with the State of Kentucky for the purpose of conducting its pharmaceutical operations.

46. According to ARCOS data, CVS distributed prescription opioids into Kentucky from 2006 to 2019. Additionally, CVS dispensed prescription opioids in Kentucky from 2006 to 2019.

47. CVS has held numerous resident pharmacy licenses in Kentucky since at least 2006. Its active licenses have expiration dates on June 30, 2025. On information and belief, CVS is using these licenses to continue dispensing prescription opioids in Kentucky.

48. As described in this Complaint, CVS has had multiple instances in which it has unlawfully distributed and/or dispensed controlled substances and/or engaged in acts of mail or

wire fraud in support of the Opioid Promotion Enterprise. From this pattern of instances, it can be inferred that CVS's policies and procedures have failed to adapt and change in order to prevent the diversion of prescription opioids. On that basis, Plaintiff alleges on information and belief that CVS continues to operate in ways that enable the diversion of prescription opioids.

b. Walgreens

49. Defendant Walgreen Co. is an Illinois corporation with its principal place of business in Illinois. Walgreen Co. affirmatively registered with the State of Kentucky and maintains an agent in Frankfort, KY.

50. Defendant Walgreen Eastern Co., Inc. ("WEC") is a New York corporation with its principal place of business in Illinois.

51. Defendant Walgreens Boots Alliance, Inc., is a Delaware corporation with its principal place of business in Illinois.

52. Walgreen Co., WEC and Walgreens Boots Alliance, Inc. are collectively referred to herein as "Walgreens."

53. Walgreens promoted, distributed, and dispensed prescription opioids throughout the United States and in Kentucky. Walgreens has a multitude of subsidiaries and agents for whom Walgreens affirmatively registered with the State of Kentucky for the purpose of conducting its pharmaceutical operations.

54. According to ARCOS data, Walgreens distributed prescription opioids into Kentucky from 2006 to 2019. Additionally, Walgreens dispensed prescription opioids in Kentucky from 2006 to 2019.

55. Walgreens has held numerous resident pharmacy licenses in Kentucky. Many of its active licenses have an expiration date on June 30, 2025. On information and belief, Walgreens is using these licenses to continue dispensing prescription opioids in Kentucky.

56. As described in this Complaint, Walgreens has had multiple instances in which it has unlawfully distributed and/or dispensed controlled substances and/or engaged in acts of mail or wire fraud in support of the Opioid Promotion Enterprise. From this pattern of instances, it can be inferred that Walgreens's policies and procedures have failed to adapt and change in order to prevent the diversion of prescription opioids. On that basis, Plaintiff alleges on information and belief that Walgreens continues to operate in ways that enable the diversion of prescription opioids.

c. Walmart

57. Defendant Walmart Inc. f/k/a Wal-Mart Stores, Inc. is a Delaware corporation with its principal place of business in Arkansas. Walmart Inc. affirmatively registered with the State of Kentucky and maintains an agent in Frankfort, KY.

58. Defendant Wal-Mart Stores East, LP is a Delaware limited partnership with its principal place of business in Arkansas. Wal-Mart Stores East, LP affirmatively registered with the State of Kentucky and maintains an agent in Frankfort, KY.

59. Walmart Inc. and Wal-Mart Stores East, LP are collectively referred to as "Walmart." At all times relevant to this Second Amended Complaint, Wal-Mart distributed, dispensed, and promoted prescription opioids throughout the United States and in Kentucky.

60. Walmart has a multitude of subsidiaries and agents for whom Walmart affirmatively registered with the State of Kentucky for the purpose of conducting its pharmaceutical operations.

61. According to ARCOS data, Walmart distributed prescription opioids into Kentucky from 2006 to 2019, and Walmart dispensed prescription opioids in Kentucky from 2006 to 2019.

62. Walmart has held numerous resident pharmacy licenses in Kentucky. Many of its active licenses have expiration dates on June 30, 2025. On information and belief, Walmart is using these licenses to continue dispensing prescription opioids in Kentucky.

63. As described in this Complaint, Walmart has had multiple instances in which it has unlawfully distributed and/or dispensed controlled substances and/or engaged in acts of mail or wire fraud in support of the Opioid Promotion Enterprise. From this pattern of instances, it can be inferred that Walmart's policies and procedures have failed to adapt and change in order to prevent the diversion of prescription opioids. On that basis, Plaintiff alleges on information and belief that Walmart continues to operate in ways that enable the diversion of prescription opioids.

2. Unnamed Manufacturing Associates

a. Janssen and Associated Companies

64. Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

65. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which was formerly known as Janssen Pharmaceutica, Inc. J&J is the only company that owns over 10% of Janssen Pharmaceuticals, Inc.'s stock. Janssen Pharmaceuticals, Inc.'s profits inure to J&J's benefit. J&J controls the development, sale, and marketing of Janssen Pharmaceuticals, Inc.'s drugs.

66. J&J and Janssen Pharmaceuticals, Inc. (collectively, "Janssen") are or have been in the business of manufacturing, selling, promoting, and/or distributing opioids (including Duragesic (fentanyl), Nucynta (tapentadol), and Ultram (tramadol)) throughout the United States and in Kentucky.

67. J&J actively promoted tramadol as safer than other opioids. When evidence began to mount of significant problems with addiction and substance misuse related to tramadol, Janssen worked actively to prevent it from being added to the list of controlled substances. It was finally

scheduled in 2014. Shortly after the drug was approved, problems with abuse and dependence began increasing rapidly. Instead of alerting the FDA of the need to schedule tramadol, J&J and Janssen, in the early 2000s, formed a "Independent Steering Committee" ("ISC") associated with the so-called Scientific Advisory Board of the RADARS System (formed by Purdue and discussed elsewhere) in order to lobby regulators against scheduling the drug. The ISC was ostensibly formed to monitor abuse of tramadol. But the real objective of the ISC was to placate the FDA into approving tramadol as a Schedule IV drug (rather than a Schedule II controlled substance). When it was formed, J&J executives even referred to the project as forming a sort of "SWAT Team," which made presentations across the country, to attempt to persuade various states not to put tramadol products in a more restrictive regulatory category. The SWAT Team was successful. Tramadol was not listed as a scheduled drug at all, not even Schedule IV. The FDA would, in 2014, classify Tramadol as a Schedule IV drug, rather than a Schedule II drug like most narcotics. It remains, to this day, a Schedule IV drug.

68. As described in this Complaint, Janssen has had multiple instances in which it has unlawfully distributed controlled substances and/or engaged in acts of mail or wire fraud in support of the Opioid Promotion Enterprise. From this pattern of instances, it can be inferred that Janssen's policies, practices, and procedures have failed to adapt and change in order to prevent the excessive use, misuse, and diversion of prescription opioids. On that basis, Plaintiff alleges on information and belief that Janssen continues to operate in ways that enable the excessive use, misuse, and diversion of prescription opioids.

69. Noramco, Inc. is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. Noramco, Inc. made and continues to make active pharmaceutical ingredients ("APIs") for opioid painkillers.

70. As described in this Complaint, Noramco has had multiple instances in which it has unlawfully distributed controlled substances and/or engaged in acts of mail or wire fraud in support of the Opioid Promotion Enterprise. From this pattern of instances, it can be inferred that Noramco's policies, practices, and procedures have failed to adapt and change in order to prevent the excessive use, misuse, and diversion of prescription opioids. On that basis, Plaintiff alleges on information and belief that Noramco continues to operate in ways that enable the excessive use, misuse, and diversion of prescription opioids.

b. Allergan and Associated Companies

71. Allergan plc is an Irish public limited company with its principal place of business in Dublin, Ireland.

72. Allergan Finance, LLC is a Nevada limited liability company headquartered in Madison, New Jersey. Allergan Finance, LLC is a wholly owned subsidiary of Allergan plc.

73. Allergan Sales, LLC is incorporated in Delaware and headquartered in Irvine, California.

74. Allergan USA, Inc. is incorporated in Delaware and headquartered in Madison, New Jersey. Allergan USA, Inc. is a wholly owned subsidiary of Allergan plc.

75. Allergan plc; Allergan Finance, LLC; Allergan Sales, LLC; and Allergan USA, Inc. are collectively referred to as "Allergan."

76. Watson Laboratories, Inc. ("Watson") is a Nevada corporation with its principal place of business in Corona, California.

77. Actavis Pharma, Inc. (f/k/a Watson Pharma Inc.) ("Actavis Pharma") is a Delaware corporation with its principal place of business in New Jersey.

78. Actavis LLC (f/k/a Actavis Inc.) ("Actavis LLC") is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

79. Watson, Actavis Pharma, and Actavis LLC are collectively referred to as "Actavis."

80. Allergan and Actavis have manufactured, promoted, marketed, advertised, and sold branded opioids nationwide and in Kentucky, including Kadian (morphine) and Norco (hydrocodone/acetaminophen). Kadian and Norco were voluntarily discontinued at the end of 2020, but existing inventory continued to be shipped after that time.

81. Watson received approval of the New Drug Application ("NDA") for branded Norco in February 1997 and sold and marketed this opioid.

82. In 2008, Actavis, Inc. (n/k/a Allergan Finance, LLC) acquired the opioid Kadian through its subsidiary, Actavis Elizabeth LLC, which had been the contract manufacturer of Kadian since 2005. Since 2008, Kadian's label has identified the following entities as the manufacturer or distributor of Kadian: Actavis Elizabeth LLC; Actavis Kadian LLC; Actavis Pharma, Inc.; and Allergan USA, Inc.

83. In 2012, Watson acquired Actavis, Inc., and the combined company took the Actavis name. Prior to its 2012 acquisition by Watson, Actavis produced twelve different generic opioids.

84. In 2013, Actavis acquired Warner Chilcott plc; these two companies were combined and incorporated in Ireland as Actavis plc. In March 2015, Actavis plc purchased Allergan, Inc. and adopted the name Allergan plc.

85. In 2016, Teva Ltd. acquired Actavis (i.e., Watson, Actavis LLC, and Actavis Pharma) from Allergan plc. Following the sale of Actavis to Teva, Allergan continued to sell Kadian and Norco until the discontinuation in late 2020.

86. According to ARCOS data, Actavis opioids were distributed into Kentucky from 2006 to 2019.

87. As used in this Complaint, "Allergan" also refers to predecessor entities for whose conduct Allergan remains liable, including Actavis.

88. As described in this Complaint, Allergan has had multiple instances in which it has unlawfully distributed controlled substances and/or engaged in acts of mail or wire fraud in support of the Opioid Promotion Enterprise. From this pattern of instances, it can be inferred that Allergan's policies, practices, and procedures failed to adapt and change in order to prevent the excessive use, misuse, and diversion of prescription opioids. On that basis, Plaintiff alleges, on information and belief, that Allergan, until it discontinued selling prescription opioids, continued to operate in ways that enable the excessive use, misuse, and diversion of prescription opioids.

c. AbbVie

89. Abbott Laboratories, Inc. is a subsidiary of Abbott Laboratories. Abbott Laboratories and Abbott Laboratories, Inc. are referred to collectively as "Abbott."

90. In 2002, Abbott acquired the pharmaceutical assets of BASF SE, which included Knoll Pharmaceuticals (Knoll Pharmaceuticals and its successor entities are referred to as "Knoll").

91. AbbVie, Inc. ("AbbVie"), is a Delaware corporation with its principal place of business in North Chicago, Illinois.

92. AbbVie was formed to affect a separation (the "AbbVie Spinoff" or the "Spinoff") of certain of Abbott's business operations, principally what Abbott described as its "research-based proprietary pharmaceuticals business," from Abbott's other operations. Effective January 1, 2013, AbbVie took title to all Abbott assets and assumed all liabilities relating to the business segments transferred to it.[11] The precise scope of the business units transferred to AbbVie is not public

[11] Separation and Distribution Agreement by and between Abbott Laboratories and AbbVie Inc. (Nov. 28, 2012).

information. Upon information and belief, based on its acquisition of most if not all of Abbott's "research-based proprietary pharmaceuticals business," AbbVie is liable (jointly and severally with Abbott) for Abbott's pre-Spinoff opioid-related liabilities. Following the Spinoff, Abbott remained in the pharmaceutical business and never took any affirmative steps to disclaim its participation in the conspiratorial conduct alleged herein.

93. In addition to being liable for certain of Abbott's pre-Spinoff conduct as a matter of contract and successorship law, AbbVie continued Abbott's practices, including upon information and belief, through the acts of its shared employees (including Jerry Eichorn, head of sales at Abbott in the 1990s who later became a senior marketing executive at AbbVie), and continued to engage in actionable conduct in relation to opioids.

94. Prior to its acquisition by Abbott, Knoll manufactured, promoted, and sold the opioids Vicodin (hydrocodone/acetaminophen), Vicoprofen (hydrocodone/ibuprofen), and Dilaudid (hydromorphone). Prior to the Spinoff, Abbott manufactured and sold Vicodin, Vicoprofen, and Dilaudid. Following the Spinoff, AbbVie continued to manufacture and sell Vicodin and Vicoprofin until it voluntarily discontinued them in late 2017.

95. AbbVie has maintained wholesale drug distributor licenses in Kentucky since at least 2012. These licenses remain active with expiration dates of June 30, 2025 or September 30, 2035.

96. According to ARCOS data, AbbVie opioids were distributed into Kentucky from 2006 to 2019.

97. On May 23, 2020, AbbVie acquired Allergan plc, including Allergan Finance, LLC; Allergan Sales, LLC; and Allergan USA, Inc. along with Allergan's liability for its conduct

associated with prescription opioids. Allergan continued to sell Norco and Kadian during the period of AbbVie's ownership.

98. As described in this Complaint, AbbVie (and its predecessor Abbott) has had multiple instances in which it has unlawfully distributed controlled substances and/or engaged in acts of mail or wire fraud in support of the Opioid Promotion Enterprise. From this pattern of instances, it can be inferred that AbbVie's policies, practices, and procedures failed to adapt and change in order to prevent the excessive use, misuse, and diversion of prescription opioids. On that basis, Plaintiff alleges, on information and belief, that AbbVie, until it discontinued selling prescription opioids, continued to operate in ways that enable the excessive use, misuse, and diversion of prescription opioids.

d. Teva

99. Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli company with its principal place of business in Petach Tikva, Israel.

100. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in Pennsylvania and is a wholly owned subsidiary of Teva Ltd.

101. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In October 2011, Teva Ltd., acquired Cephalon, which became a wholly owned subsidiary of Teva Ltd.

102. Teva Ltd., Teva USA, and Cephalon are collectively known as "Teva".

103. Teva manufactured, promoted, advertised, distributed, and sold branded—Actiq (fentanyl) and Fentora (fentanyl)—and generic opioids in the United States and Kentucky.

104. Teva has maintained wholesale drug distributor licenses in Kentucky since at least 2007. These licenses remain active with an expiration date of September 30, 2025. On information and belief, Teva's prescription opioids continue to be distributed in Kentucky.

105. According to ARCOS data, Teva opioids were distributed into Kentucky from 2006 to 2019.

106. As described in this Complaint, Teva has had multiple instances in which it has unlawfully distributed controlled substances and/or engaged in acts of mail or wire fraud in support of the Opioid Promotion Enterprise. From this pattern of instances, it can be inferred that Teva's policies, practices, and procedures have failed to adapt and change in order to prevent the excessive use, misuse, and diversion of prescription opioids. On that basis, Plaintiff alleges, on information and belief, that Teva continues to operate in ways that enable the excessive use, misuse, and diversion of prescription opioids.

e. Indivior

107. Indivior, Inc. f/k/a Reckitt Benckiser Pharmaceuticals, Inc. ("Indivior") is a Delaware corporation with its principal place of business in Richmond, Virginia.

108. Indivior manufactured, promoted, advertised, distributed, and sold opioids—Sublocade (buprenorphine), Subutex (buprenorphine), Suboxone tablet (buprenorphine, naloxone), and Suboxone film (buprenorphine/naloxone).

109. As described in this Complaint, Indivior has had multiple instances in which it has unlawfully distributed controlled substances and/or engaged in acts of mail or wire fraud in support of the Opioid Promotion Enterprise. From this pattern of instances, it can be inferred that Indivior's policies, practices, and procedures failed to adapt and change in order to prevent the excessive use, misuse, and diversion of prescription opioids. On that basis, Plaintiff alleges, on information and belief, that Indivior has continued to operate in some ways that enable the excessive use, misuse, and diversion of prescription opioids.

110. In April 2019, the U.S. Department of Justice announced that a federal grand jury indicted Indivior for engaging in its illicit nationwide scheme. The indictment charged Indivior

with conspiracy to commit wire fraud, mail fraud, and health care fraud, as well as twenty-two counts of wire fraud, four counts of mail fraud, and one count of health care fraud.[12]

111. In July 2019, Indivior agreed to pay $1.4 billion to resolve its potential criminal and civil liability following its indictment in April 2019. To resolve its potential criminal liability, Indivior agreed to forfeit $647 million of its illicit proceeds and not to manufacture, market, or sell Schedule I, II, or III controlled substances in the United States for three years following the agreement. To resolve its potential civil liability, Indivior agreed to pay $700 million to resolve claims that its Suboxone marketing caused false claims to be submitted to government healthcare programs.[13]

112. In June 2020, Indivior's former chief executive officer, Shaun Thaxter, pleaded guilty to a one-count information charging him with misrepresenting the safety of Suboxone to a state Medicaid program.[14]

113. In July 2020, Indivior pleaded guilty to a one-count felony information and agreed to pay a total of $600 million to resolve its potential criminal and civil liability associated with its false and misleading Suboxone marketing and promotion. Indivior further agreed to permanently disband its Suboxone sales force and take steps to prevent the promotion of Suboxone to health care providers at a high risk of inappropriate prescribing.[15]

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[12] *Id.*

[13] Press Release, Dep't of Just., Justice Department Obtains $1.4 Billion from Reckitt Benckiser Group in Largest Recovery in a Case Concerning an Opioid Drug in United States History (July 11, 2019), https://www.justice.gov/opa/pr/justice-department-obtains-14-billion-reckitt-benckiser-group-largest-recovery-case (last visited Feb. 21, 2024).

[14] Press Release, Dep't of Just., Opioid Manufacturer Indivior's Chief Executive Officer Pleads Guilty In Connection With Drug Safety Claims (June 30, 2020), https://www.justice.gov/opa/pr/opioid-manufacturer-indivior-s-chief-executive-officer-pleads-guilty-connection-drug-safety (last visited Feb. 27, 2024).

[15] Press Release, Dep't of Just., Indivior Solutions Pleads Guilty To Felony Charge And Indivior Entities Agree To Pay $600 Million To Resolve Criminal And Civil Investigations As Part Of DOJ's Largest Opioid Resolution (July 24, 2020), https://www.justice.gov/opa/pr/indivior-solutions-pleads-guilty-felony-charge-and-indivior-entities-agree-pay-600-million (last visited Feb. 21, 2024).

114. In August 2020, Indivior's former Global Medical Director, Timothy Baxter, pleaded guilty to a one-count misdemeanor information. Baxter admitted that an Indivior employee he supervised sent inaccurate drug-safety information to a state Medicaid agency.[16]

115. In June 2023, Indivior and 42 states negotiated a nationwide $102.5 million settlement with Indivior resolving the states' lawsuit alleging that Indivior sought to disrupt generic competition, monopolize the opioid market, and destroy the tablet medication market. The states alleged, *inter alia*, that Indivior's attempted monopolization and anti-competitive activities limited access to life-saving medication-assisted treatments for patients suffering from OUD.

f. Hikma

116. Hikma Pharmaceuticals USA Inc. f/k/a West-Ward Pharmaceuticals Corp. ("Hikma") is a wholly owned subsidiary of Hikma Pharmaceuticals plc. Hikma Pharmaceuticals USA Inc. is a Delaware corporation with its principal place of business in Berkeley Heights, New Jersey.

117. Hikma manufactured, promoted, advertised, distributed, and sold generic opioids, including hydromorphone, oxymorphone, and methadone products, in the United States and Kentucky.

118. Hikma has maintained wholesale drug distributor licenses in Kentucky since at least 2006. These licenses remain active with expiration dates ranging from June 30, 2025 and September 30, 2024, respectively. On information and belief, Hikma's opioids continue to be distributed in Kentucky.

[16] Press Release, Dep't of Just., Opioid Manufacturer Indivior's Former Global Medical Director Pleads Guilty In Connection With Drug Safety Claims (Aug. 31, 2020), https://www.justice.gov/usao-wdva/pr/opioid-manufacturer-indivior-s-former-global-medical-director-pleads-guilty-connection (last visited Feb. 27, 2024).

119. According to ARCOS data, Hikma opioids were distributed into Kentucky from 2006 to 2019.

120. As described in this Complaint, Hikma has had multiple instances in which it has unlawfully distributed controlled substances and/or engaged in acts of mail or wire fraud in support of the Opioid Promotion Enterprise. From this pattern of instances, it can be inferred that Hikma's policies, practices, and procedures failed to adapt and change in order to prevent the excessive use, misuse, and diversion of prescription opioids. On that basis, Plaintiff alleges, on information and belief, that Hikma continues to operate in ways that enable the excessive use, misuse, and diversion of prescription opioids.

121. In or around February 2024, Hikma settled substantially similar claims brought against it by state Attorneys General for $150 million.[17] The state Attorneys General alleged that from 2006 to 2021, Hikma failed to monitor and report suspicious opioid orders from potentially illegal distributors, even while its personnel knew their systems to monitor suspicious orders were inadequate and prone to failure.[18]

g. Grünenthal

122. Grünenthal GmbH is a German company with its principal place of business in Aachen, Germany. It concentrates on manufacturing, marketing, and selling prescription pain medications, including opioids.

123. Among its many affiliates are two U.S. subsidiaries: Grünenthal USA, Inc. and Grünenthal Pharmaceuticals, Inc. (collectively, with other Grünenthal entities, including the

[17] *See* Press Release, Office of the Attorney General of New York, Attorney General James Secures $150 Million Multistate Settlement in Principle with Hikma Pharmaceuticals to Help Combat Opioid Crisis (Feb. 1, 2024), https://ag.ny.gov/press-release/2024/attorney-general-james-secures-150-million-multistate-settlement-principle-hikma (last visited Feb. 29, 2024).
[18] *Id.*

German parent, "Grünenthal"). Grünenthal USA, Inc. was a Delaware corporation with its principal place of business in New Jersey; it was dissolved in 2023. Grünenthal Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business in New Jersey.

124. Grünenthal GmbH controlled the activities of its U.S. subsidiaries and acted through them to engage in conduct within the United States as described in this Complaint. It has also independently engaged in conduct in the United States, including negotiating with and executing agreements with licensees for tramadol, tapentadol, and INTAC.[19] In the course of this conduct, both Grünenthal GmbH and the U.S. subsidiaries that it controlled engaged in predicate acts alleged in this Complaint and/or conspired with other members of the Opioid Promotion Enterprise. It did so in part by using the mails and/or wires within the United States.

125. Grünenthal invented and developed tramadol, which it launched in 1981. J&J licensed the drug from Grünenthal and introduced into the U.S. market as Ultram, which continues to be distributed and dispensed in the United States. Grünenthal also invented and developed tapentadol, which it licensed to Janssen in 2003. Grünenthal then approved Janssen's transfer for the license in 2015 to Depomed.[20] Dissatisfied with Depomed's inability to increase sales of the opioid, Grünenthal agreed in 2017 to transfer the license to Collegium in hopes of driving increased

[19] *See*, *e.g.*, 2nd Amendment to the Development, License and Supply Agreement entered on December 18, 2007, https://www.sec.gov/Archives/edgar/data/1100962/000144530514000793/ex101392grunenthal2ndamend.htm (showing Grünenthal GmbH contracting with Endo in "Malvern, PA 19355, USA"); Consent Agreement, https://www.sec.gov/Archives/edgar/data/1267565/000155837020005738/coll-20200331xex10d5.htm (showing Grünenthal GmbH contracting in 2020 with Assertio Therapeutics, Inc. of "Lake Forest, IL 60045, USA" and Collegium of "Stoughton, MA 02072").

[20] Press Release, Grünenthal Grp., Grünenthal GmbH Granted Its Consent to Transfer the License Rights for Nucynta (tapentadol) in the U.S. from Janssen Pharmaceuticals, Inc. to Depomed, Inc. (Jan. 15, 2015).

sales.[21] Collegium continues to market and sell Nucynta in the U.S. under the license from Grünenthal.

126. Grünenthal also developed INTAC technology that purported to make pills more difficult to crush and then abuse by insufflation (snorting). It licensed this technology to Endo and Purdue. Opioids using this technology were distributed into and dispensed in Kentucky.

127. As described in this Complaint, Grünenthal has had multiple instances in which it engaged in acts of mail or wire fraud in support of the Opioid Promotion Enterprise. From this pattern of instances, it can be inferred that Grünenthal's policies, practices, and procedures failed to adapt and change in order to prevent the excessive use, misuse, and diversion of prescription opioids. On that basis, Plaintiff alleges on information and belief that Grünenthal continues to operate in ways that enable the excessive use, misuse, and diversion of prescription opioids.

h. Mallinckrodt

128. Mallinckrodt LLC, Mallinckrodt plc, and SpecGx LLC (collectively, "Mallinckrodt") manufactured, promoted, advertised, distributed, and sold branded and generic opioids. Mallinckrodt manufactures four branded opioids: Exalgo (hydromorphone), Roxicodone (oxycodone), Xartemis XR (oxycodone/acetaminophen), and Methadose (methadone). Mallinckrodt is also one of the largest manufacturers of generic opioids.

i. Purdue

129. Purdue Pharma, L.P.; Purdue Pharma, Inc.; and The Purdue Frederick Company (collectively, "Purdue") manufactured, promoted, advertised, distributed, and sold branded opioids, including opioids OxyContin (oxycodone), MS Contin (morphine), Butrans

[21] *New Partnership for the Commercialization of Nucynta in the U.S. Territory*, PR Newswire (Dec. 5, 2017), https://www.prnewswire.com/news-releases/new-partnership-for-the-commercialization-of-nucynta-in-the-us-territory-662000683.html.

(buprenorphine), Hysingla ER (hydrocodone), Dilaudid (hydromorphone), Dilaudid-HP (hydromorphone), and Targiniq ER (oxycodone/naloxone).

j. Endo

130. Endo Pharmaceuticals Inc. is a wholly owned subsidiary of Endo Health Solutions, Inc. (collectively, "Endo"). Endo manufactured, promoted, advertised, distributed, and sold branded—Percocet (oxycodone/paracetamol), Opana (oxymorphone), and Percodan (oxycodone/aspirin)—and generic opioids.

131. Although not named as defendants because they are seeking reorganization under Chapter 11 of the Bankruptcy Code, Mallinckrodt, Purdue and Endo participated with Defendants along with others as part of the Opioid Promotion Enterprise.

132. Collectively, Janssen, Grünenthal, Teva, AbbVie, Allergan, Indivior, Mallinckrodt, Purdue, and Endo and Hikma are referred to as the "Manufacturing Associates" and "Manufacturing Defendants." Although not named as defendants in this action, they are included as participants in any conduct alleged of the "Defendants" as a collective entity.

133. Specific opioids manufactured by the Manufacturing Associates are described in this Complaint as examples only. Plaintiff maintains that Defendants' liability arises from their conduct related to opioids generally and is not limited to opioid products specifically described in this Complaint.

3. Unnamed Distributor Associates

a. AmerisourceBergen

134. AmerisourceBergen Drug Corporation ("ABDC") is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania. As of August 30, 2023, ABDC and affiliated companies have been rebranded as Cencora.

135. ABDC distributed and promoted prescription opioids throughout the United States and in Kentucky, including through its subsidiary, Xcenda L.L.C. ("Xcenda"), a Florida limited liability company.

136. According to ARCOS data, ABDC distributed prescription opioids into Kentucky from 2006 to 2019.

137. ABDC has maintained wholesale drug distributor licenses in Kentucky since at least 2010. The current license, issued on June 21, 2019, has an expiration date on September 30, 2025. On information and belief, ABDC is using these licenses to continue distributing prescription opioids into Kentucky.

138. As described in this Complaint, ABDC has had multiple instances in which it has unlawfully distributed controlled substances and/or engaged in acts of mail or wire fraud in support of the Opioid Promotion Enterprise. From this pattern of instances, it can be inferred that ABDC's policies and procedures have failed to adapt and change in order to prevent the diversion of prescription opioids. On that basis, Plaintiff alleges, on information and belief, that ABDC continues to operate in ways that enable the diversion of prescription opioids.

b. Anda

139. Anda, Inc. ("Anda") is a Florida corporation with its principal place of business in Weston, Florida.

140. In October 2016, Teva Ltd. acquired Anda from Allergan plc.

141. Anda has distributed and promoted prescription opioids throughout the United States and in Kentucky.

142. According to ARCOS data, Anda distributed prescription opioids into Kentucky from 2006 to 2019.

143. Anda has maintained wholesale drug distributor licenses in Kentucky since at least 1997. These licenses remain active with expiration dates on September 30, 2025. On information and belief, Anda is using these licenses to continue distributing prescription opioids into Kentucky.

144. As described in this Complaint, Anda has had multiple instances in which it has unlawfully distributed controlled substances and/or engaged in acts of mail or wire fraud in support of the Opioid Promotion Enterprise. From this pattern of instances, it can be inferred that Anda's policies and procedures have failed to adapt and change in order to prevent the diversion of prescription opioids. On that basis, Plaintiff alleges, on information and belief, that Anda continues to operate in ways that enable the diversion of prescription opioids.

c. Cardinal

145. Cardinal Health, Inc. ("Cardinal") is an Ohio corporation with its principal place of business in Dublin, Ohio.

146. Cardinal distributed and promoted prescription opioids throughout the United States and in Kentucky.

147. According to ARCOS data, Cardinal distributed prescription opioids into Kentucky from 2006 to 2019.

148. Cardinal has maintained wholesale drug distributor licenses in Kentucky since at least 2006. Its current license, issued on April 1, 2009, has an expiration date on September 30, 2025. On information and belief, Cardinal is using these licenses to continue distributing prescription opioids into Kentucky.

149. As described in this Complaint, Cardinal has had multiple instances in which it has unlawfully distributed controlled substances and/or engaged in acts of mail or wire fraud in support of the Opioid Promotion Enterprise. From this pattern of instances, it can be inferred that Cardinal's policies and procedures have failed to adapt and change in order to prevent the diversion

of prescription opioids. On that basis, Plaintiff alleges, on information and belief, that Cardinal continues to operate in ways that enable the diversion of prescription opioids.

d. H.D. Smith

150. H.D. Smith, LLC (f/k/a H.D. Smith Wholesale Drug Co.) ("H.D. Smith") distributed prescription opioids throughout the United States and in Kentucky.

151. H.D. Smith LLC's sole member is H.D. Smith Holdings, LLC, whose sole member is H.D. Smith Holding Company, a Delaware corporation with its principal place of business in Illinois. In January 2018, ABDC acquired H.D. Smith.

152. According to ARCOS data, H.D. Smith distributed prescription opioids into Kentucky from 2006 until 2019.

153. As described in this Complaint, H.D. Smith has had multiple instances in which it has unlawfully distributed controlled substances and/or engaged in acts of mail or wire fraud in support of the Opioid Promotion Enterprise. From this pattern of instances, it can be inferred that H.D. Smith's policies and procedures have failed to adapt and change in order to prevent the diversion of prescription opioids. On that basis, Plaintiff alleges on information and belief that H.D. Smith continues to operate in ways that enable the diversion of prescription opioids.

e. Henry Schein

154. Henry Schein, Inc. ("Schein") is a Delaware corporation with its principal place of business in Melville, New York.

155. Schein distributed and promoted prescription opioids throughout the United States and in Kentucky.

156. Schein has maintained wholesale drug distributor licenses in Kentucky since at least 1998. These licenses remain active with expiration dates ranging from June 30, 2025 to September

30, 2025. On information and belief, Schein is using these licenses to continue distributing prescription opioids into Kentucky.

157. As described in this Complaint, Schein has had multiple instances in which it has unlawfully distributed controlled substances and/or engaged in acts of mail or wire fraud in support of the Opioid Promotion Enterprise. From this pattern of instances, it can be inferred that Schein's policies and procedures have failed to adapt and change in order to prevent the diversion of prescription opioids. On that basis, Plaintiff alleges on information and belief that Schein continues to operate in ways that enable the diversion of prescription opioids.

f. McKesson

158. McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business in Irving, Texas.

159. McKesson distributed and promoted prescription opioids throughout the United States and in Kentucky.

160. According to ARCOS data, McKesson distributed prescription opioids into Kentucky from 2006 to 2019.

161. McKesson has maintained wholesale drug distributor licenses in Kentucky since at least 2009. These licenses remain active with expiration dates ranging from June 30, 2025 to September 30, 2025. On information and belief, McKesson is using these licenses to continue distributing prescription opioids into Kentucky.

162. As described in this Complaint, McKesson has had multiple instances in which it has unlawfully distributed controlled substances and/or engaged in acts of mail or wire fraud in support of the Opioid Promotion Enterprise. From this pattern of instances, it can be inferred that McKesson's policies and procedures have failed to adapt and change in order to prevent the

diversion of prescription opioids. On that basis, Plaintiff alleges, on information and belief, that McKesson continues to operate in ways that enable the diversion of prescription opioids.

g. Kroger

163. The Kroger Co. is an Ohio corporation with its principal place of business in Cincinnati, Ohio.

164. Kroger Limited Partnership I is an Ohio limited partnership.

165. Kroger Limited Partnership II is an Ohio limited partnership.

166. The Kroger Co., Kroger Limited Partnership I, and Kroger Limited Partnership II are collectively referred to as "Kroger."

167. Kroger has distributed, dispensed, and promoted prescription opioids throughout the United States. Kroger continues to dispense prescription opioids.

168. Kroger Limited Partnership II has held resident pharmacy licenses in Kentucky since at least 2003. These licenses expire on June 30, 2025.

169. As described in this Complaint, Kroger has had multiple instances in which it unlawfully distributed and/or dispensed controlled substances and/or engaged in acts of mail or wire fraud in support of the Opioid Promotion Enterprise. From this pattern of instances, it can be inferred that Kroger's policies and procedures have failed to adapt and change in order to prevent the diversion of prescription opioids. On that basis, Plaintiff alleges, on information and belief, that Kroger continues to operate in ways that enable the diversion of prescription opioids.

h. Albertsons

170. Albertsons Companies, Inc. (f/k/a Albertsons LLC) is a Delaware corporation with its principal place of business in Boise, Idaho.

171. Albertson's LLC is a Delaware limited liability company with its principal place of business in Boise, Idaho. Albertson's LLC is a wholly owned subsidiary of Albertsons Companies, Inc.

172. Safeway, Inc. is a Delaware corporation with its principal place of business in Pleasanton, California. Safeway, Inc. is a wholly owned subsidiary of Albertsons Companies, Inc.

173. Albertsons Companies, Inc., Albertson's LLC, and Safeway, Inc. are collectively known as "Albertsons."

174. On information and belief, Albertsons pharmacies also ordered controlled substances through McKesson, while Safeway pharmacies prior to 2015 ordered controlled substances primarily through Cardinal Health.

175. As described in this Complaint, Albertsons has had multiple instances in which it unlawfully distributed and/or dispensed controlled substances and/or engaged in acts of mail or wire fraud in support of the Opioid Promotion Enterprise. From this pattern of instances, it can be inferred that Albertsons's policies and procedures have failed to adapt and change in order to prevent the diversion of prescription opioids. On that basis, Plaintiff alleges on information and belief that Albertsons continues to operate in ways that enable the diversion of prescription opioids.

i. Giant Eagle

176. Giant Eagle, Inc. ("Giant Eagle") is a Pennsylvania corporation with its principal place of business in Pittsburgh, Pennsylvania.

177. HBC Service Company ("HBC") is an operating division of Giant Eagle.

178. Giant Eagle, Inc. and HBC Service Company are collectively referred to as "Giant Eagle."

179. On information and belief, Giant Eagle both self-distributed opioids and sourced opioids from McKesson and AmerisourceBergen.

180. Giant Eagle has distributed, dispensed, and promoted prescription opioids throughout the United States.

181. Giant Eagle continues to dispense prescription opioids.

j. Publix

182. Publix Super Markets, Inc. ("Publix") is a Florida corporation with its principal place of business in Lakeland, Florida.

183. Upon information and belief, Publix both self-distributed opioids and sourced opioids from AmerisourceBergen and Anda.

184. Publix has distributed, dispensed, and promoted prescription opioids throughout the United States.

185. According to ARCOS data, Publix distributed prescription opioids from 2006 until at least 2019.

186. Publix continues to dispense prescription opioids to this day.

187. Defendants Walgreens, CVS, and Walmart, and Distributor Associates ABDC, Anda, Cardinal, H.D. Smith, Schein, McKesson, Kroger, Albertsons, Publix, Giant Eagle, and Walmart are collectively referred to at times herein as the "Distributor Defendants." Walgreens, CVS, Kroger, Albertsons, Publix, Giant Eagle, and Walmart are collectively referred to herein as the "National Retail Pharmacies."

188. AmerisourceBergen, Cardinal, McKesson, Schein, and H.D. Smith distributed opioids nationwide and in Kentucky. Walgreens, CVS, Walmart, and Kroger distributed opioids to their own retail stores nationwide and in Kentucky. All of these opioids were then purchased by consumers.

189. The Distributor Defendants marketed and promoted opioids to pharmacies and, in some cases, hospitals, health care providers, and patients.

190. Walgreens, Walmart, CVS, Kroger, and Albertsons also dispensed and continue to dispense opioids to consumers in Kentucky and nationally. These entities also promoted opioids and served as a conduit between the manufacturers of opioids and customers.

4. Unnamed Associate McKinsey

191. Defendant McKinsey & Company, Inc. is a corporation organized under the laws of the state of New York. McKinsey's principal place of business is located at 711 Third Avenue, New York, NY 10017.

192. Defendant McKinsey Holdings, Inc. is a Delaware corporation with its principal place of business located at 711 Third Avenue, New York, NY 10017.

193. Defendant McKinsey & Company, Inc. United States is a Delaware corporation with its principal place of business located at 711 Third Avenue, New York, NY 10017.

194. Defendant McKinsey & Company, Inc. Washington D.C. is a Delaware corporation with its principal place of business located at 711 Third Avenue, New York, NY 10017.

195. Upon information and belief, McKinsey & Company, Inc. is the parent company of McKinsey & Company Holdings, Inc., which is itself the parent company of both McKinsey & Company, Inc. United States and McKinsey & Company, Inc. Washington D.C. Upon information and belief, each subsidiary corporation is wholly owned by its parent. Despite the corporate form, McKinsey began as a partnership and still refers to its senior employees as "partners." Those partners are the firm's shareholders. Collectively, these four Defendants are referenced throughout as "McKinsey."

196. McKinsey is a global management consultancy with offices in over 130 cities in 65 countries, including the following United States cities: Atlanta, GA; Austin, TX; Houston, TX; Dallas, TX; San Francisco, CA; Los Angeles, CA; Redwood City, CA; Boston, MA; Charlotte, NC; Chicago, IL; Cleveland, OH; Denver, CO; Detroit, MI; Miami, FL; Miramar, FL; Tampa, FL;

Minneapolis, MN; Summit, NJ; New York, NY; Philadelphia, PA; Pittsburgh, PA; Seattle, WA; St. Louis, MO; Stamford, CT; Waltham, MA; and Washington, D.C.

197. McKinsey is registered to do business in all fifty states.

198. While McKinsey does not itself manufacture, distribute, or dispense prescription opioids, its role in the Opioid Promotion Enterprise was to advise other members how to increase the sale and use of prescription opioids. McKinsey accordingly does not itself have obligations under the Controlled Substances Act or its state equivalents, but rather conspired with other Defendants that did have such obligations.

5. Defendants' Agents and Affiliated Persons

199. Defendants include the above-referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships, and divisions to the extent that they are engaged in the manufacture, promotion, distribution, sale, and/or dispensing of opioids.

200. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority. Defendants conspired and coordinated, including as accessories and/or accomplices, and to commit (and actually committed) the unlawful acts complained of herein with the unnamed Manufacturer, Distributor, and Retail Pharmacy Defendants identified, herein.

IV. DEFENDANTS CREATED ILLEGITIMATE DEMAND FOR OPIOIDS.

201. Defendants conspired, coordinated and worked together, with the unnamed co-conspirators, and through other industry organizations and groups to expand and promote as safe the widespread use of opioids for non-cancer medical conditions, to convince acute care hospitals

to include an extensive range of opioids on their formularies, and to create illegitimate demand for dangerous opioids. Defendants' actions were unlawful and contrary to information known to only them, used amongst themselves to engage in the concerted action to perpetuate unlawful acts, including unlawful violations of the CSA, RICO and various Kentucky laws, including KRS 218A.180(4); 902 KAR 55:080; 902 KAR 55:105 § 3; KRS 218A.180(5); KRS 218A.180; 201 KAR 2:100; KRS 315.335; KRS 315.121.[22]

202. Opioid use had previously been confined to highly specialized end-of-life- or cancer-care settings because opioids are highly addictive and their use can and does result in fatal overdoses. Defendants, however, collectively launched a misinformation campaign to inflate the market for these drugs, peddling them as safe and appropriate for use to treat a range of chronic conditions and severely downplaying how addictive and dangerous they are. Then, through these actions, Defendants flooded communities across the country, including in Kentucky, with unreasonable, unjustifiable quantities of opioids, dispensing opioids not intended for a legitimate medical purpose, distributing opioids without fulfilling their obligations under the CSA, jointly devising and implementing policies to permit expansion of the market, and deliberately turned a blind eye to rising rates of opioid dependence, OUD, and diversion. Defendants collectively (and successfully) committed this conduct for their mutual financial gain.

203. As a direct result of Defendants' conduct—that includes acts not warranted by law and/or from neglect of a duty imposed by law—, they created a condition of an opioid epidemic, which is prejudicial to the health, comfort, safety, property, sense of decency, and/or morals of the citizens at large in Kentucky and, more specifically, Plaintiff, its property and its mission of treating patients. Plaintiff suffered and will continue to suffer unique and special damages and

[22] *See supra* n.3. indicating Defendants are not now required to answer the specific RICO allegations of this paragraph within the bellwether, Track 23.

injury—differing from those suffered by the community at large—as a result of Defendants' conduct and the nuisance caused.

A. Opioids are dangerous and highly addictive narcotics.

204. The use of opioids leads to physical dependency. Opioid use also leads to tolerance in which the brain physiologically adapts to the presence of opioids and then demands greater and greater doses over time to achieve the same effects. Millions of people who have been prescribed opioids have developed OUD.[23] According to the CDC, as many as 1 in 4 people receiving prescription opioids long term in a primary care setting struggles with addiction.[24]

205. As their need for opioids becomes more acute, many individuals initially prescribed opioids seek prescriptions from multiple doctors, buy black-market prescription opioids, or turn to drugs like heroin and illicitly produced fentanyl.

B. Defendants set out to change the best practices for the use of opioids.

206. Defendants were aware that opioids pose significant risks and that the long-term safety and efficacy of opioids for chronic pain has never been established in medical literature. Nevertheless, in a deliberate plot to counter legitimate fears, Defendants collectively and through agreements intentionally and unlawfully engaged in a misinformation campaign about the risks and effects of opioid use. They did so to convince prescribers and the public that opioids are appropriate—and even necessary—to treat common chronic conditions, such as back pain and headaches.

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[23] *See* Nat'l Inst. on Drug Abuse, Medications to Treat Opioid Use Disorder Research Report (rev. Dec. 2021), https://nida.nih.gov/download/21349/medications-to-treat-opioid-use-disorder-research-report.pdf.

[24] Prescription Opioids, Ctrs. for Disease Control & Prevention (last rev. Aug. 29, 2017), https://www.cdc.gov/opioids/basics/prescribed.html; see also Anna Lembke, Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked and Why It's So Hard to Stop 22 (2016) (hereinafter, Drug Dealer, MD) ("[A]s many as 56 percent of patients receiving long-term prescription opioids for low back pain, for example, progress to addictive opioid use, including patients with no prior history of addiction.").

207. The consensus in the medical community—prior to Defendants' concerted campaign of deception—was that opioids were not safe for long-term use or for the treatment of chronic pain. Opioids were reserved for specialized uses, such as treatment of cancer pain or palliative care at the end of life.

208. To maximize profits, Defendants conspired and collectively plotted to normalize the treatment of chronic, noncancer pain with highly addictive prescription opioids. This is clearly described by the Department of Veterans Affairs and the Department of Defense:

> Prior to the 1980s, O[pioid] T[herapy] was rarely used outside of severe acute injury or post-surgical pain, primarily due to concern for tolerance, physical dependence, and addiction. As the hospice and palliative care movement began defining end-of-life care in the U.S. during the 1980s and emphasizing the importance of pain relief, OT increasingly became a mainstay for cancer and end-of-life pain. Efforts to destigmatize the use of prescription opioids for chronic non-terminal pain encompassed primary care providers and the public. The efforts led to an unprecedented increase in opioid prescribing for chronic non-terminal pain. Chronic pain management became synonymous with L[ong-term] OT in the 1990s and the first decade of the 2000s with significant numbers of patients in pain clinics receiving LOT. Despite the absence of long-term safety or efficacy data, OT for chronic non-terminal pain became a mainstay of therapy.[25]

209. This tentative expansion of opioid use for palliative care and cancer pain provided an opportunity that Defendants—collectively and through conspiracy—exploited directly and collectively through their unsupported and misleading characterization of the appropriate use and risk-benefit profiles of their own products and indirectly through financing and influencing organizations that promoted increasing the use of opioids to treat an ever-wider variety of chronic conditions.

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[25] The Opioid Therapy for Chronic Pain Work Group, U.S. Dep't of Veterans Affairs & U.S. Dep't of Defense, *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain* (3d ed. 2017), https://www.va.gov/HOMELESS/nchav/resources/docs/mental-health/substance-abuse/VA_DoD-CLINICAL-PRACTICE-GUIDELINE-FOR-OPIOID-THERAPY-FOR-CHRONIC-PAIN-508.pdf (emphasis added) (hereinafter *VA/DoD 2017 Opioid Guidelines*).

210. Much of the early work in changing the approach to pain management was made possible through grants by the Robert Wood Johnson Foundation ("RWJF"), which funded initiatives to expand the use of prescription opioids to treat both end-of-life and cancer pain as well as chronic, nonmalignant pain. A primary grantee was the University of Wisconsin Pain & Policy Study Group ("UW-PPSG") that initially promoted opioid use for end-of-life and cancer care before expanding its advocacy to the use of opioids for other chronic conditions.

211. One of the primary ways in which Defendants achieved their objective was by manipulating, funding, and, in some cases, founding, ostensibly independent organizations to advocate for the wider use of opioids to treat all forms of chronic, noncancer pain, particularly through treatment guidelines.

212. Such guidelines play a role in establishing best practices for clinicians. Recognizing this fact of modern medical practice, Defendants set their sights on three targets to change prescribing practices and the culture surrounding pain treatment: (1) the Joint Commission of the Accreditation of Healthcare Organizations ("JCAHO"), which established standards that hospitals had to follow to remain accredited; (2) the Federation of State Medical Boards ("FSMB"), which established model standards for doctor discipline; and (3) the Veterans Administration ("VA"), which directly ran a great number of hospitals and clinics. Defendants' collective goal was to convince these organizations to issue treatment guidelines encouraging the regular evaluation of pain and its treatment with prescription opioids.

213. Defendants succeeded in this through their concerted actions and misrepresentations. The VA and FSMB guidelines supporting the assessment of pain and its treatment via prescription opioids were issued in 1998. JCAHO and the opioid industry (through another front group, the National Pharmaceutical Council) issued joint guidelines in 1999. The

changes in these guidelines were so significant from the then-current best practices that hospitals were given two years—until 2001—to implement them.

214. The promulgation of pain as a vital sign, and the corresponding slogan, "pain is the fifth vital sign," illustrates the radical scope of this change. The addition of pain, a subjective and effectively unquantifiable metric, to the list of vital signs essentially required doctors to treat pain as equivalently important to blood pressure or respiration rate because patients should always receive treatment to bring their vital signs back into a normal range. In the context of an overburdened health care system, out of necessity, doctors turned to the fastest-acting tool at their disposal to reduce pain to an acceptable level: prescription opioids.

215. In the interval before the JCAHO guidelines went into effect, the Pain & Policy Studies Group (PPSG) at University of Wisconsin (UW-PPSG) (also funded by the RWJF and many of the unnamed associates identified herein) led lobbying efforts and media campaigns directed at legislatures, doctors, hospitals, and even patients to persuade the medical community to adopt these novel practices. The influence on acute care hospitals was significant. According to one expert:

> The funding is really what made it possible for the Pain & Policy Study Group to roll out this new paradigm around pain treatment . . . . Also, the Joint Commission was involved in that process, and they actually received content that was created by Purdue Pharma. That was disseminated to hospitals who were trying to make Joint Commission accreditation. They used videos produced by Purdue. They used documents created by Purdue in order to change the paradigm around opioid prescribing, including promoting opioid[s]—including promoting pain as the fifth vital sign.

216. As a result of the paradigm shift in the approach to treating chronic pain orchestrated by Defendants, who acted through trade organizations, Front Groups and with the Unnamed associates listed above, "[d]octors were taught that prescribing opioids for chronic pain was evidence-based medicine even though there was no evidence to support it." Simply put, "these

different factions manipulated and misrepresented, deliberately or otherwise, medical science to serve their own agendas."[26] This change affected nearly every aspect of medical practice.

217. Articles were published in the media describing pain as the fifth vital sign, the assessment of pain as a required practice in hospitals and clinics around the country, and the elimination of pain as a patient right.

218. Pain scores emphasized the absence of pain as a patient right and documented pain in patient records. Those records became the basis for enforcement activities resulting from JCAHO accreditation audits, as well as CMS' Hospital Consumer Assessment of Healthcare Providers and Systems surveys (HCAHPS), which tied reimbursements to patients' perspectives of hospital care and, more particularly, the hospital's use of medication for pain control. The JCAHO and CMS scores effectively forced doctors to treat pain with opioids.

219. The 1998 FSMB guidelines spurred prescriptions by removing the threat of discipline for doctors who prescribed opioids in violation of what had been accepted best practices prior to Defendants' intervention. Reasonable physicians could conclude that failing to prescribe opioids would expose them to discipline. FSMB collaborates closely with UW-PPSG at the direction of, and with funding from, the associates identified, herein.

220. Medical schools began teaching pain as the fifth vital sign and the assessment and treatment of pain as part of the core curriculum.

221. Continuing Medical Education (CME) programs led by the opioid industry, their Front Groups, and KOLs regularly characterized the use of prescription opioids as best practices even to the exclusion of other recognized and less dangerous treatment modalities.

[26] Drug Dealer, MD, *supra*, at 57.

222. Once a significant number of patients with chronic, noncancer pain were receiving opioid "therapy," best practices were caused to evolve to treat the consequences: titration to higher doses for patients presenting with the industry-promoted concept of "pseudoaddiction" as well as higher doses and longer use of opioids when patients presented with withdrawal-like symptoms.

223. The concept of blaming the patient for drug-seeking behavior took root. Prescribed opioids served as a gateway drug, with some patients advancing to illicit heroin and other drugs to address their withdrawal cravings after states and regulatory authorities later took steps to reduce opioid prescriptions and prosecute doctors running pill mills.

C. Defendants jointly promoted falsehoods about the risks and benefits of prescription opioids.

224. Defendants were uniquely aware that opioids posed (and still pose) significant risks and that the long-term safety and efficacy of opioids for chronic pain has never been established in medical literature. Nevertheless, Defendants collectively, through coordination, intentionally and unlawfully engaged in a misinformation campaign to convince prescribers, legislators, and the public that opioids are appropriate—and even necessary—to treat chronic pain.

225. The intended effect (which was, in fact, achieved) was to increase opioid prescriptions, thereby increasing Defendants' profit from distributing, and dispensing their opioids. While some of the falsehoods listed below were initially promoted by unnamed Manufacturers, Distributors, and/or Retail Pharmacies, Defendants worked collectively with each other, with those unnamed associates, and/or through industry organizations to promote and further embed those falsehoods in furtherance of their conspiracy and financial motivations, with each of these acts concerted and collective.

1. Falsehood#1: The risk of addiction to opioids is low.

226. Defendants were uniquely aware that opioids are highly addictive, that tolerance and physical dependency develop rapidly, and that prescription opioids confer an increased risk of addiction and overdose even in patients who take their medication as prescribed. By the mid-1990s, a number of studies had already demonstrated a high incidence of OUD among chronic pain patients. Defendants and the unnamed associates claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to support that claim. None of them have acknowledged, retracted, or corrected their false statements.

227. A common Method, used by various Manufacturing Associates, was to point to a one paragraph letter to the editor in the *New England Journal of Medicine* in 1980.[27]

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

[27] Jane Porter & Hershel Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 New Eng. J. Med., 123 (1980), http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221.

228. While first Purdue and then other Manufacturing Associates first asserted that their opioids were not addictive, Dr. Jick later explained, "that's not in any shape or form what we suggested in our letter."[28]

229. The enormous impact of Defendants' and the unnamed associates' misleading amplification of the Porter & Jick Letter was well documented in another letter published in the *NEJM* on June 1, 2017.

230. Subsequent reviews found that the prevalence of misuse following opioid prescriptions for chronic pain was between 21% and 29%, with a prevalence of addiction between 8% and 12%.[29]

2. Falsehood #2: It is easy to identify people at high risk for addiction.

231. Defendants and the unnamed associates falsely asserted that even if some patients are at risk of opioid addiction, health care providers can effectively identify those patients using screening tools or questionnaires and then manage the risk of addiction by imposing heightened monitoring on patients deemed "at risk."

232. Defendants and unnamed associates created and disseminated these tools to perpetuate the myth that only patients with easily identifiable traits are at risk for addiction and that, by implication, opioids are safe for everyone else.

3. Falsehood#3: Signs of addictive behavior are "pseudoaddiction" requiring more opioids.

233. Defendants and the unnamed associates claimed that the signs of opioid addiction were merely symptoms of "pseudoaddiction," meaning "behaviors (that mimic addictive

[28] Taylor Haney & Andrea Hsu, *Doctor Who Wrote 1980 Letter on Painkillers Regrets that It Fed Opioid Crisis*, NPR (June 16, 2017), https://www.npr.org/sections/health-shots/2017/06/16/533060031/doctor-who-wrote-1980-letter-on-painkillers-regrets-that-it-fed-the-opioid-crisi.
[29] Vowles, et al., *supra*.

behaviors) exhibited by patients with inadequately treated pain." Moreover, Defendants and the unnamed associates claimed that pseudoaddiction should be treated by giving patients higher doses of opioids. The message (delivered in associate-funded publications, CMEs and office visits) was that patients exhibiting classic signs of opioid misuse—for example, asking for more and higher doses of opioids, self-escalating their doses, or claiming to have lost prescriptions in order to get more opioids—did not have or were not developing OUD, but rather simply suffering from *under*-treatment of their pain.

234. In reality, such behaviors are indicators of OUD. Defendants knew no legitimate evidence supported their claim that doctors should treat signs of addiction as "pseudoaddiction."

4. Falsehood #4: Addicted patients are "untrustworthy" "abusers".

235. Despite their knowledge of opioid's contraindications and addictive properties, Defendants and the unnamed associates began to blame addiction, overdose, and death on "abuse," in effect blaming patients for their OUD—rather than accurately identifying the culprit as the marketing and resulting excessive prescription of dangerous opioids.

236. Defendants and the unnamed associates knew that the tactic of blaming addiction on untrustworthy patients was a lie.

237. While there are patients who obtain opioids for the express purpose of misusing them, at the relevant time such patients were a small minority, approximately2% of opioid prescriptions.[30] The burgeoning harm from opioid use and misuse that has harmed St. Elizabeth is overwhelmingly a problem of false marketing and unconstrained distribution and dispensing of the drugs—not a problem caused by patients.

[30] *Although Relatively Few, "Doctor Shoppers" Skew Opioid Prescribing*, Nat'l Inst. on Drug Abuse (May 27, 2014), https://web.archive.org/web/20230209135632/https://archives.drugabuse.gov/news-events/nida-notes/2014/05/although-relatively-few-doctor-shoppers-skew-opioid-prescribing.

5. Falsehood #5: Opioid withdrawal can be avoided by tapering.

238. Most patients who have been taking opioids regularly will, upon stopping treatment, experience physically and psychologically painful withdrawal. Defendants deceptively represented that withdrawal is easily managed by tapering a patient's dose of opioids and failed to disclose that withdrawal would be more severe and tapering less effective in patients who had used opioids for a prolonged period.

6. Falsehood #6: Opioid doses can be increased without limit or increased risk.

239. Defendants misleadingly claimed there was no ceiling on the amount of opioids that can be taken safely. With higher doses, and particularly with the addition of short-acting or immediate-release opioids, the risk of fatal overdose and other adverse effects grows.

240. Defendants and the unnamed associates directed these misrepresentations, in key part, toward prescribers, including those working in hospitals. Because patients develop a tolerance to opioids' analgesic effects, achieving long-term pain relief requires constantly increasing the dose. Not only are stronger doses more expensive, but patients who take larger doses or who escalate to larger doses faster are much more likely to remain on opioids for a longer time. Defendants knew that promotion of these changes increased their revenues against the backdrop of increased adverse effects uniquely known to them.[31]

241. Defendants and the unnamed associates aggressively educated doctors to prescribe stronger doses of opioids, including assuring doctors that proper treatment necessitated the prescription of higher dosages of opioids. The cartel maintained notes and statistics on how to effectively influence prescribers.

[31] *See* Heidi N. Overton, et al., *Opioid-Prescribing Guidelines for Common Surgical Procedures: An Expert Panel Consensus*, 227 J. Am. Coll. Surgeons 411 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6353661/pdf/nihms-989596.pdf.

242. Defendants and the unnamed associates knew of (or were uniquely positioned to know of) the greater dangers posed by high-dose opioids.

7. Falsehood #7: Long-term opioid use improves functioning.

243. Defendants and the unnamed associates misrepresented to patients and prescribers that long-term opioid use can improve the quality of life of patients suffering from chronic conditions.

244. Defendants and those entities knew (or were uniquely positioned to know) that these claims were incorrect. Defendants and their associates knew that no controlled long-term studies credibly established any improved quality of life in chronic pain patients treating with opioids—or even that they were effective in improving patients' chronic pain over the long term.[323334]

[32] *Promoting Safer and More Effective Pain Management*, Ctrs. for Disease Control, https://www.cdc.gov/drugoverdose/pdf/guidelines_factsheet-patients-a.pdf; *2016 CDC Guideline*, *supra*, at 20.

[33] *See also* Warning Letter from Thomas Abrams, Dir., Div. of Mktg., Adver., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis US (Feb. 18, 2010), https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., Div. of Mktg., Adver., & Commc'ns, U.S. Food & Drug Admin., to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008) (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

[34] *2016 CDC Guideline*, *supra*, at 20.

245. Rather, the evidence demonstrates that opioids are ineffective for the treatment of chronic pain, worsen patients' health, and do not contribute to improvement in functional outcomes, and, when used for chronic pain, actually worsen pain and functioning. [35],[36]

246. In addition, Defendants knew that patients using opioids for chronic pain were at heightened risk of developing OUD and that long-term opioid use can cause debilitating deterioration in a patient's quality of life.[37]

8. Falsehood #8: Opioids are safer than other pain medications.

247. Defendants and the unnamed associates misleadingly claimed that opioids are safer than traditional painkillers like acetaminophen and nonsteroidal anti-inflammatory drugs ("NSAIDs") by exaggerating the risks of NSAIDs and trivializing, or simply omitting, the risks of opioids.

248. These risks, which are not shared or are of much less concern with acetaminophen and NSAIDs, include hyperalgesia;[38] hormonal dysfunction;[39] decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly;[40] neonatal abstinence syndrome; and potentially fatal interactions with alcohol.[41]

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[35] Andrea D. Furlan, et al., *Opioids for Chronic Noncancer Pain: A Meta-Analysis of Effectiveness and Side Effects*, 174 Can. Med. Ass'n J. 1589 (2006), https://www.cmaj.ca/content/cmaj/174/11/1589.full.pdf.
[36] Thomas Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1503 (2016), https://www.nejm.org/doi/full/10.1056/NEJMp1515917 (hereinafter "*Reducing the Risks of Relief*").
[37] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, 60 Sonoma Med. (Fall 2009).
[38] Woodcock-Kolodny Letter, *supra*.
[39] Harry W. Daniell, *Hypogonadism in Men Consuming Sustained-Action Oral Opioids*, 3 J. Pain 377 (2001), https://www.jpain.org/article/S1526-5900(02)00032-9/fulltext.
[40] *See* Bernhard M. Kuschel, et al., *The Risk of Fall Injury in Relation to Commonly Prescribed Medications Among Older People – A Swedish Case-control Study*, 25 Eur. J. Pub. Health 527 (2014), https://www.ncbi.nlm.nih.gov/pubmed/25085470.
[41] Karen H. Seal, et al., Association of Mental Health Disorders with Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan, 307 J. Am. Med. Ass'n 940 (2012), https://jamanetwork.com/journals/jama/fullarticle/1105046.

249. As a result of this false claim, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant.

9. Falsehood #9: Ostensibly "abuse-deterrent" formulations are safer.

250. As the opioid crisis intensified, Defendants capitalized on the problem they had created—the widespread diversion and misuse of opioids—by marketing purportedly "abuse-deterrent formulations" ("ADFs") that make pills harder to crush, snort, or dissolve and inject.

251. However, "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse."[42]

252. Defendants and the unnamed associates also knew that these formulations did nothing to reduce the likelihood that a patient taking a pill orally for medical use would develop OUD.

253. Walgreens, Walmart, and CVS cooperated with unnamed associates (including Indivior, Endo, Purdue and Grünenthal) in the increased prescription and fill rates of ADF's without regard to and purposefully and actively avoiding their duties under the CSA.

10. Falsehood #10: Short-acting opioids should be used to treat chronic, noncancer "breakthrough" pain.

254. Defendants and the unnamed associates embedded as fact the notion that short-acting or immediate-release opioids could and should be taken in conjunction with long-acting or extended-release opioids to treat "breakthrough pain" for a variety of common chronic conditions. While breakthrough pain is recognized in cancer patients, Defendants collaborated to broaden the definition for the benefit of their sales and without regard for providers and/or their patients.

[42] Ctrs. for Disease Control & Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain, 2016*, Morbidity & Mortality Weekly Rep. (Mar. 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm (hereinafter, "*2016 CDC Guidelines*").

255. Further, some short-acting opioids used to treat breakthrough cancer pain contain fentanyl. Defendants knew, or had reason to know, that Fentanyl treatments for breakthrough pain are deadly for people who are not already tolerant of opioids. They have never been accepted as a safe treatment for non-cancer chronic pain.

256. As part of their campaign to expand the market for their opioid products, Defendants marketed high-risk fentanyl-based opioids to fill that feigned "need" in patients taking opioids for chronic conditions, even though Defendants knew that the safety of such use had never been established and that fentanyl-based opioids come with heightened risk.

11. Falsehood #11: Despite heightened risk factors, the elderly and veterans can safely use opioids.

257. Defendants and the unnamed associates aggressively marketed opioids as safe and effective for high-risk groups. For example, Defendants marketed opioids to veterans, even though opioids can cause fatal interactions with benzodiazepines, a common treatment for PTSD. Defendants did so without addressing these risks. Defendants funded, wrote, published and disseminated literature that promoted opioid use by veterans, without disclosing the absence of clinical trials and medical ethics.

258. Defendants and the unnamed associates aggressively marketed opioids to elderly patients, even though the elderly suffer the same risk of dependence and tolerance that other opioid users experience.

259. In sum, each of these misrepresentations regarding the use of opioids to treat chronic pain was either not supported by or was contrary to the scientific evidence. Through these and other misrepresentations, Defendants misinformed and continue to misinform the medical community and the public about the risks of opioid use.

D. Defendants used a campaign of misinformation to publicize these falsehoods and convince prescribers, legislators, and the public of their truth.

260. Defendants worked collectively and in concert to publicize their falsehoods and did not merely spread their misinformation through their own employees and publications. Recognizing the influence if the misrepresentations came from purportedly "independent" sources, Defendants collectively and through coordination targeted, funded and used multiple, mutually reinforcing channels to spread their deceptive claims, avoid and breach their obligations under the CSA, including: (1) direct, targeted communications with prescribers by sales representatives or "detailers"; (2) Front Groups with the appearance of independence from the Manufacturing Associates; (3) independent organizations that were captured by Defendants; (4) Key Opinion Leaders ("KOLs"), that is, doctors paid by the Manufacturing Associates to promote their pro-opioid message; (5) mechanisms of disseminating their misleading messages through reputable organizations; (6) CME programs controlled and/or funded by the Manufacturing Associates; (7) branded advertising; (8) unbranded advertising; (9) publications; and (10) speakers' bureaus and programs. They performed these acts for the purpose of maximizing their financial gain. Defendants and the unnamed associates also invested in overcoming resistance from insurance and health plans to pay for opioids prescribed for chronic, non-cancerous conditions. Strategies to overcome insurers' refusal to cover opioids included call centers, to help patients navigate the insurance and insurance appeals process, as well as working with doctors on the same issues.

1. Defendants used "detailers" to disseminate their misrepresentations directly to prescribers.

261. The Manufacturing Associates, who Defendants coordinated their activities with, employed numerous sales representatives (also called "detailers") to call and visit healthcare providers and deliver deceptive messages about opioids. These in-person sales calls are called "detailing." Through these joint activities, Defendants and the unnamed associates identified and

targeted susceptible prescribers by, for example, focusing on primary care doctors, who were more likely to prescribe drugs to chronic pain patients, but less likely to be educated about treating pain; such doctors were more likely to accept the Manufacturing Associates' misrepresentations. The representatives were trained to evade prescribers' questions regarding opioids' addictiveness and to misrepresent and conceal facts relating to opioid safety. The Defendants and unnamed associates prepared brochures, videos, and other marketing materials containing misrepresentations for sales representatives to distribute to providers during in-person visits. The Defendants and various associates devoted meaningful, coordinated and overlapping resources to direct sales contacts with doctors. Detailing had the intent and effect of making the detailed prescriber more willing to prescribe not only the detailing manufacturer's opioids, but also opioids as a class of drugs. The associates studied this fact and maintained information to increase the success of their outreach.

2. Defendants used Front Groups to promote greater opioid use.

262. Defendants, led by the Manufacturing Associates and trade organizations, spread misinformation through front groups that were created to appear to be independent, neutral, third parties (the "Front Groups") but were in fact funded and influenced by Defendants.

263. Defendants and the Associates viewed this funding of Front Groups as a *quid pro quo*.

264. Some of the Front Groups were professional associations whose independence was compromised by their reliance on funding from Defendants and unnamed associates and their use of that funding to engage in activities that promoted the greater use of prescription opioids in the absence of credible clinical justification. Examples of these sorts of Front Groups include without limitation the American Pain Society, the American Geriatrics Society, and the American Academy of Pain Medicine, the National Association of Chain Drug Stores and the National Association of Boards of Pharmacy.

265. The Front Groups released patient education materials, treatment guidelines, and CMEs that, despite the absence of evidence, overstated the benefits and understated the risks of using opioids to treat chronic pain. Defendants then used, referenced, and distributed these ostensibly neutral materials to support their marketing claims in coordination with each other and the unnamed associates.

266. Defendants funded these Front Groups in order to ensure supportive messages from seemingly neutral and credible third parties, and this funding did, in fact, ensure such supportive messaging. Defendants coordinated with the unnamed associates in forming a coalition on controlled substances to ensure that any restrictions on distribution and dispensing opioids were not overly broad, and worked in partnership with the HDA, NACDS, and National Board of Pharmacies to avoid DEA actions, strategize to limit the DEA's enforcement authority, and to avoid enforcement actions for Defendants' willful violations of the CSA.

267. Defendants and the unnamed associates made millions of dollars' worth of contributions to various Front Groups, the Front Groups amplified messages of Defendants and the unnamed associates to promote overprescription and use of opioids (through falsehoods and other means above), while also disregarding regulatory obligations, avoiding enforcement of their violative actions, and challenging legal efforts to hold Defendants responsible for their unlawful actions. [43]

a. American Pain Foundation

268. American Pain Foundation ("APF") was a prominent Front Group.

269. Although APF held itself out as an independent patient advocacy organization, it was funded almost entirely by the pharmaceutical industry, including Defendants.

[43] *Id.* at 12.

270. This funding was not disinterested. The basis of a grant to the organization was the desire to invest in nonprofits that shared Defendants and the unnamed associates' business interests, all geared toward building a coalition for the mutual economic benefit of the cartel.

271. APF also developed materials and initiatives intended to influence prescribers and patients through the media, arguing, for example, that under-treatment of pain is a greater concern than addiction.

272. APF also published a guide that contained multiple misrepresentations regarding opioid use, including that opioids are an appropriate first-line therapy for chronic pain.[44]

273. *Treatment Options* also misrepresented the risk of death as a reason to avoid NSAIDs and warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

274. *Treatment Options* ignored NSAIDs, they are available over the counter because they have no real risk of causing anyone to develop a substance use disorder. Opioids are controlled substances precisely because they carry that risk.

275. The publication further dismissed the concern that an "average person" could become addicted to opioids and blamed this concern for doctors' hesitation to write opioid prescriptions and for the fact that opioids were "under-used," while misrepresenting that withdrawal can be prevented by slowly reducing the dose without addressing that many people have an extremely difficult time weaning themselves off opioids once they become physically dependent.[45]

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[44] Am. Pain Found., *Treatment Options: A Guide for People Living with Pain*, https://web.archive.org/web/20220812235117/https://ce4less.com/Tests/Materials/E019Materials.pdf (last visited Aug. 25, 2023 as of Aug. 12, 2022) (hereinafter *Treatment Options*).

[45] *Id.*

276. APF also developed the National Initiative on Pain Control (the "NIPC"), which ran a facially unaffiliated website, *painknowledge.org*. NIPC promoted itself as an education initiative led by its expert leadership team, [46] but it was Endo that substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing the programs' content; and distributing NIPC materials.

277. A website developed by APF/NIPC proclaimed many of the falsehoods listed above, including specifically that "[p]eople who take opioids as prescribed usually do not become addicted," that opioid dosages should be raised until "you are on the right dose of medication for your pain," without addressing the dangers that high doses of opioids present to patients. The website listed certain adverse effects of opioids but omitted the severe adverse effects of hyperalgesia, immune system and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death, and it misrepresented that opioids would improve function. [47]

278. *Pain: Opioid Facts*, a brochure available on *Painknowledge.org*, misrepresented that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted."[48]

279. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but did not disclose the

[46] Accredited programs are reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies.

[47] *Pain: Opioid Therapy*, painknowledge.org, https://web.archive.org/web/20101007083722/http://painknowledge.org/patiented/pdf/B697_%20Patient%20Handout_FINAL.pdf (last accessed July 13, 2021 as of Jan. 19, 2012).

[48] *Pain: Opioid Facts*, painknowledge.org, https://web.archive.org/web/20120112051109/http://www.painknowledge.org/patiented/pdf/Patient%20Education%20b380_b385%20%20pf%20opiod.pdf (last accessed July 14, 2021 as of Jan. 19, 2012).

significant hardships that often accompany cessation of use. The publication also falsely indicated that opioids were more effective for improved functioning than other analgesics.

280. Defendants adopted and/or coordinated with each of the unnamed associates for each of these improper actions and misrepresentations, and others.

b. American Academy of Pain Medicine and the American Pain Society

281. The American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies that received substantial and regular funding from Defendants and Associates who were thus able to wield influence over them.

282. Through 2019, AAPM received lavish funding totaling nearly $10 million from opioid manufacturers.

283. In 1997, AAPM and APS jointly issued a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk of addiction to opioids was low.[49] Employees or paid advocates of the Manufacturing Associates participated in the drafting of this statement, which remained on AAPM's website until 2011.

284. The AAPM offered a CME on *The Truth About Pain Management* in conjunction with a 2007 annual meeting where the chief lecturer had financial ties to Cephalon and Purdue.[50]

285. AAPM and APS issued their own guidelines in 2009 (the "2009 Guidelines") with Defendants' assistance, prompting, involvement, and funding. Using a panel largely made up of KOLs and unnamed associates, the 2009 Guidelines made unsupported recommendations for the

[49] Am. Acad. of Pain Med. & Am. Pain Soc'y, The Use of Opioids for the Treatment of Chronic Pain (1997).
[50] The Truth, *supra*.

use of opioids to treat chronic pain and the use of screening tools to identify patients at a purportedly high risk of addiction. [51]

286. Defendants and the unnamed associates widely cited and promoted the 2009 Guidelines without disclosing the lack of supporting evidence or their financial backing of the guidelines' authors.

c. The University of Wisconsin Pain and Policy Study Group

287. The Pain and Policy Study Group ("PPSG") at the University of Wisconsin was instrumental in providing purportedly scientific, academic and legislative rationale for the increased use of prescription opioids. Led by two non-physicians: Aaron Gilson (who holds a PhD in social welfare) and David Joranson (who holds a master's in social work), the PPSG relentlessly advocated for the removal of restrictions designed to monitor and keep careful controls over the use of dangerous prescription opioids. The group's goal was to increase the use of prescription opioids by downplaying consequences associated with the widespread availability of prescription opioids, including misuse and substance use disorder.

288. All the while, the UW-PPSG was accepting millions of dollars from unnamed associates, including Purdue and the Robert Wood Johnson Foundation, closely affiliated with and receiving financial support from J&J and its stock.

289. UW-PPSG used resources, particularly from the RWJF, to pressure the Joint Commission to change its standards for treating pain and pressure FSMB to change its model regulations on pain treatment so as to require treatment with prescription opioids.

[51] Roger Chou, et al., Am. Pain Soc'y & Am. Acad. of Pain Med. Opioids Guidelines Panel, *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10 J. Pain 113 (2009), https://www.jpain.org/action/showPdf?pii=S1526-5900%2808%2900831-6.

d. Alliance for Patient Access

290. Founded in 2006, the Alliance for Patient Access ("AfPA") styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care."[52] As of June 2017, the AfPA listed 30 "Associate Members and Financial Supporters," including the unnamed associates J&J, Endo, Mallinckrodt, Purdue, and Cephalon, and unnamed associates substantially funded the AfPA's board members[53]

291. Among its activities, AfPA issued a white paper, *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse.*[54] The white paper criticizes prescription monitoring programs, which are vital tools in reducing diversion and opioid misuse.

e. American Geriatrics Society

292. The American Geriatrics Society ("AGS") was another Front Group with systematic connections to the unnamed associates with whom Defendants coordinated. The AGS was used by those entities to target the elderly by advocating for increased treatment of the elderly with opioids. Through actions of Defendants and the coordination of unnamed associates, AGS developed guidelines that recommended the expansive use of opioids and argued that addiction risks from opioids were very low, including the 2009 AGS Guidelines recommended that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy" despite "lowquality of evidence" supporting the recommendation.[55] These Guidelines misrepresented

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[52] Anne Marie Hummel, *New Treatments Provide Hope for Respiratory Patients*, Am. Ass'n for Respiratory Care (May 19, 2021), https://www.aarc.org/an21-new-treatments-provide-hope-for-respiratory-patients/; *see also About AfPA*, Alliance for Patient Access, https://allianceforpatientaccess.org/about (last visited Aug. 25, 2023). References herein to AfPA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

[53] All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica's Dollars for Docs database, https://projects.propublica.org/docdollars/.

[54] Inst. for Patient Access, *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, (Oct. 2013), http://alliancebpm.wpengine.com/wp-content/uploads/2016/05/2014-11-13-pt-white-paper-final-1-1-pdf.pdf.

[55] *Id.* at 1342.

that—despite no reliable evidence—"the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."

f. American Chronic Pain Association

293. After the American Chronic Pain Association ("ACPA") was founded in 1980, it became influenced by the opioid industry, including the coordination of Defendants. The organization received funding from opioid makers, medical device manufacturers, and companies that market opioid therapies for opioid-related conditions. These payments funded materials that "appear to help sell products sold by opioid manufacturers, discussed opioid therapy while sidestepping the addictive nature of drugs, and attributed responsibility for overdoses for people who misuse opioids."[56]

g. C.A.R.E.S. Alliance

294. In 2010, Mallinckrodt created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as a "patient safety initiative which provides education and tools to healthcare professionals and patients to support responsible opioid prescribing and safe use."[57] Materials distributed by the C.A.R.E.S. Alliance include unbranded publications promoting the use of opioids to treat noncancer chronic pain that do not disclose the link to Mallinckrodt. For example, by 2012 the C.A.R.E.S. Alliance promoted the book *Defeat Chronic Pain Now!* to doctors and patients, which made many false claims and misrepresentations, including without limitation the falsehoods listed above.[58]

[56] December 2020 Senate Bipartisan Opioids Report, supra, at 10–12 (and authorities cited therein).
[57] C.A.R.E.S. All., *Fact Sheet* (Feb. 2011), https://www.justice.gov/sites/default/files/usao-ndga/legacy/2011/03/02/C.A.R.E.S.%20Alliance%20Fact%20Sheets.pdf.
[58] C.A.R.E.S. All., C.A.R.E.S. Alliance Tools: Catalog and Order Form 13 (n.d.) (hereinafter C.A.R.E.S. Alliance Tools).

295. Dr. Fishman, a regular contributor to the cartel, published a glowing review of *Defeat Chronic Pain Now!*.[59]

296. The C.A.R.E.S. Alliance worked closely with other front groups, with whom Defendants coordinated their unlawful and complained of activities.

297. The Front Groups succeeded in spreading Defendants' misinformation about opioids.

3. Defendants captured independent organizations.

298. Defendants also captured otherwise independent organizations and co-opted them as mouthpieces for their pro-opioid messages.

a. Federation of State Medical Boards

299. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. These boards have the power to license doctors, investigate complaints, and discipline physicians.

300. The FSMB finances opioid- and pain-specific programs through funding (i.e., "grants" or other payments for services) from Defendants and/or unnamed associates.[60]

301. Starting in 1998, several of the Manufacturer Defendants' Front Groups, as well as the Janssen-funded Robert Wood Johnson Foundation ("RWJF"), partnered to author the new standards of practice that would drive opioid prescribing. RWJF provided the funding, and the Front Groups, including AAPM, APS, and PPSG, "developed" the model guidelines "for state medical boards . . . for use in regulating the prescribing of controlled substances, such as opioids, in the management of chronic cancer and non-cancer pain." Critically, the FSMB, as well as each of the Front Groups that drafted the model guidelines, were all members of the Pain Care Forum

[59] Defeat Chronic Pain Now Website, *supra.*
[60] Opioid CME, CME List, https://www.cmelist.com/opioid-cme/ (last visited Aug. 25, 2023).

302. Not surprisingly, therefore, the *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (the "1998 Guidelines")[61] promoted Defendants' common message, emphasizing the treatment of pain and trivializing addiction. [62] [63]

303. The 1998 Guidelines also assured doctors that they "should not fear disciplinary action" for "prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose."

304. Defendants in coordination with the unnamed defendants heavily promoted these guidelines, citing the 1998 Guidelines and 2004 Model Policy thousands of times.[64]

305. The 1998 Guidelines inaccurately claimed that "[m]ultiple clinical studies" showed that opioids improved daily function, psychological health, and overall quality of life for those suffering from chronic pain.[65] The FSMB website described *Responsible Opioid Prescribing* as the "leading continuing medical education (CME) activity for prescribers of opioid medications."[66]

306. A 2012 update to *Responsible Opioid Prescribing* still assured physicians that "[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins."[67]

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[61] *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*, Fed. St. Med. Bds. (May 1998), https://web.archive.org/web/19990202032433/http://www.fsmb.org/pain.htm (last accessed July 13, 2021 as of Feb. 2, 1999) (hereinafter *1998 FSMB Guidelines*).
[62] 1998 FSMB Guidelines.
[63] *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*, Fed. St. Med. Bds. (May 2004), https://web.archive.org/web/20050103015118/http://www.fsmb.org/ (click "Pain Policy Research Center"; then click "Model Policy") (last accessed July 13, 2021 as of Jan. 3, 2005).
[64] John Fauber, *Follow the Money: Pain, Policy, and Profit*, MedPage Today (Feb. 19, 2012), https://www.medpagetoday.com/neurology/painmanagement/31256.
[65] Scott M. Fishman, Responsible Opioid Prescribing: A Physician's Guide (2007) (hereinafter, Responsible Opioid Prescribing).
[66] *Responsible Opioid Prescribing: A Clinician's Guide*, Fed'n St. Med. Bds., https://web.archive.org/web/20130115014329/http://www.fsmb.org/book/ (last accessed July 13, 2021 as of Jan. 15, 2013).
[67] *Id.*

b. The Joint Commission

307. The Joint Commission f/k/a the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO" prior to 2007 and "Joint Commission" thereafter) is the oldest and largest healthcare standards-setting and performance-improvement organization in the United States. JCAHO is highly influential.

308. Hospitals view loss of Joint Commission accreditation as harmful to their operations. Loss of accreditation can have implications on market share and competition.

309. Defendants and the unnamed associates made it their primary goal in the late 1990s to influence JCAHO to enact standards designating pain as the "fifth vital sign," thereby encouraging (and in some cases all but requiring) the use of opioids to treat hospital patients' pain. Defendants and the unnamed associates advanced their campaign of deception to influence JCAHO to enact favorable pain standards through Front Groups such as APF, APS, and UW-PPSG, whose efforts to advocate for the assessment and treatment of pain and to minimize the risks of addiction from opioids were financed primarily by the Robert Wood Johnson Foundation, an organization that still holds a significant amount of J&J stock.

310. Supported by Defendants and the unnamed associates, JCAHO enacted Pain Standards in 1999. Because the JCAHO Standards totally transformed the standard of care for treating pain in hospitals and other healthcare organizations, their effective date was delayed until 2001. In the interim, JCAHO, Defendants, the unnamed associates, and Front Groups and KOLs supported by Defendants and the unnamed associates engaged in a well-financed effort to persuade hospitals, prescribers, and even consumers to adopt the messages embodied in the new standards: opioids should be used to treat pain and were not addictive when so used.

311. Defendants and/or their unnamed associates provided additional financial support to JCAHO while it was developing a pain care guide and other materials to be distributed to hospitals and pain care providers that reflected the JCAHO Standards.

312. In 2000, as part of the plan discussed above to "make the whole pie bigger," Purdue discussed developing "materials for the Joint Commission on Accreditation for Healthcare Organizations (JCAHO)" that "will be distributed to hospitals across the country in our partnership with the American Pain Society."

313. That same year, Purdue sponsored a JCAHO book that falsely claimed that "there is no evidence that addiction is a significant issue when persons are given opioids for pain control."[68] It also misleadingly called doctors' concerns about addiction side effects "inaccurate and exaggerated."[69]

314. The Defendants', Associates' and Front Groups' influence resulted in change to the JCAHO standards, thereby increasing opioid prescribing and administration and modifications to formularies, including within acute care hospitals. Providers were effectively forced to comply with these new standards to the financial gain of Defendants.

4. The Manufacturing Associates paid Key Opinion Leaders to deceptively promote opioid use.

315. The Manufacturing Associates, and in coordination with Defendants, also spread misinformation through purported medical experts, known as Key Opinion Leaders ("KOLs"), whom the Manufacturing Associates paid to deliver deceptive messages because of their ability to influence their peer prescribers, while giving the inaccurate appearance that unbiased and reliable medical research supported expansion of opioid therapy.

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[68] Sonia Moghe, *Opioid History: From 'Wonder Drug' to Abuse Epidemic*, CNN (Oct. 13, 2016), https://www.cnn.com/2016/05/12/health/opioid-addiction-history/ (hereinafter *Wonder Drug*).
[69] *Id.*

a. Dr. Russell Portenoy

316. Dr. Portenoy promoted the use of opioids and minimized their risks as a spokesperson for Purdue, Defendants, and the unnamed associates. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, co-founder of Physicians for Responsible Opioid Prescribing, described him "lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling message: 'Docs have been letting patients suffer; nobody really gets addicted; it's been studied.'"[70]

317. Dr. Portenoy has now admitted that he minimized the risks of opioids[71] and that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[72]

b. Dr. Lynn Webster

318. Dr. Lynn Webster was president of AAPM in 2013 and was a Senior Advising Editor of *Pain Medicine*, the AAPM's journal.[73] Dr. Webster was the author of numerous CMEs sponsored by unnamed associates Cephalon, Endo, and Purdue. At the same time, he received significant funding from Defendants (including nearly $2 million from Cephalon).

319. Dr. Webster created and promoted the *Opioid Risk Tool*—which appeared on unnamed associates' websites—a five-question, one-minute screening tool relying on patient self-

[70] Sam Quinones, *Dreamland: The True Tale of America's Opiate Epidemic* 134 (2015).
[71] Celine Gounder, *Who Is Responsible for the Pain-Pill Epidemic?*, New Yorker (Nov. 8, 2013), https://www.newyorker.com/business/currency/who-is-responsible-for-the-pain-pill-epidemic.
[72] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall Street J. (Dec. 17, 2012), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.
[73] *CRI Lifetree Chief Medical Director Dr. Lynn Webster Named President of the American Academy of Pain Medicine (AAPM)*, Scorr Marketing (Apr. 23, 2013), https://www.scorrmarketing.com/news/cri-lifetree-chief-medical-director-dr-lynn-webster-named-president-of-the-american-academy-of-pain-medicine-aapm/; Elaine Silvestrini, *Profiting from Pain*, Drug Watch, https://www.drugwatch.com/featured/opioid-crisis-big-pharma/ (last modified June 29, 2021).

reports that incorrectly purported to allow doctors to manage the risk that their patients will misuse opioids or develop OUD.[74]

320. In 2011, Dr. Webster presented a webinar sponsored by Purdue titled *Managing Patients' Opioid Use: Balancing the Need and the Risk*. This webinar misleadingly taught that risk screening tools, urine testing, and patient agreements will prevent "overuse of prescriptions" and "overdose deaths."

c. Dr. Perry Fine

321. Dr. Fine's ties to the Manufacturing Associates are well documented. He has authored articles, testified in court cases and before state and federal committees, and argued against legislation restricting the prescription of high doses of opioids to noncancer patients.

322. Drs. Fine and Portenoy co-wrote the Endo-supported *A Clinical Guide to Opioid Analgesia*, which downplayed risks such as respiratory depression and addiction and promoted the myth that "long-term opioid therapy of an older population with no history of substance abuse is rarely associated with de novo development of abuse or addiction."[75]

d. Dr. Scott Fishman

323. Dr. Fishman was tied to and received funding from unnamed associates. He has served as an APF board member and as AAPM president and has participated yearly in numerous CME activities for which he received "market rate honoraria." He has authored publications, including seminal guides on opioid prescribing, which were funded by the Manufacturing Associates. He has also opposed legislation requiring doctors and others to consult pain specialists

[74] Lynn Webster & Rebecca Webster, Predicting Aberrant Behaviors in Opioid-Treated Patients: Preliminary Validation of the Opioid Risk Tool, 6 Pain Med. 432 (2005).
[75] Perry G. Fine & Russell K. Portenoy, *A Clinical Guide to Opioid Analgesia* 20, 34 (2004).

before prescribing high doses of opioids to noncancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest.[76]

5. Defendants disseminated their misrepresentations through Continuing Medical Education programs.

324. Defendants and the unnamed associates also distributed their false message to the medical community through countless continuing medical education ("CME") programs. Defendants controlled the content of these presentations, while deliberately giving the CMEs the illusion of neutrality, and the promoted their false messaging through them.

6. Defendants promoted specific opioid products to doctors and consumers.

325. Defendants and the unnamed associates engaged in widespread advertising campaigns touting the benefits of their branded drugs. They collectively spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they had spent in 2001.

326. The advertising also targeted consumers because Defendants and the unnamed associates knew that physicians were more likely to prescribe a drug if a patient specifically requested it. [77]

7. Defendants used unbranded advertising to promote opioid use.

327. Defendants and the unnamed associates also aggressively promoted opioids through "unbranded advertising" that generally touted their falsehoods so as to evade FDA scrutiny of their promotion.

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[76] *Incomplete Financial Disclosures*, *supra*; Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011), https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry.

[77] In one study, for example, nearly 20% of sciatica patients requesting oxycodone received a prescription for it compared with 1% of those making no specific request. John B. McKinlay, et al., *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52 Med. Care 294 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4151257/.

328. Because unbranded advertising is not required to provide balanced disclosures about a product's limits and risks, it was an effective tool to expand the overall acceptance of and demand for chronic opioid therapy.

329. For example, as early as 2001, CVS worked with Purdue and its unbranded marketing arm, Partners Against Pain ("PAP"), to challenge these (later proven) allegations that Purdue's OxyContin was being misused at alarming rates. Purdue and its partners, including CVS, used Purdue's PAP website to claim that the risk of addiction associated with OxyContin was very small.

8. Defendants funded, edited, and distributed publications that supported their misrepresentations.

330. Defendants and the unnamed associates created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be (but was not) the result of independent, objective research; and (c) was purposely calculated to shape the perceptions of hospitals (including St. Elizabeth), prescribers, patients, and payors. This literature served marketing goals, rather than scientific standards, and was intended to persuade prescribers and consumers that the benefits of long-term opioid use outweighed the risks.

331. To accomplish their goal, the Defendants and unnamed associates—sometimes through third-party consultants and/or Front Groups—commissioned, edited, and arranged for the placement in academic journals of favorable but deceptive review articles, letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or suppressing negative information that contradicted their claims or raised concerns about chronic opioid therapy. Defendants and their coordinated unnamed associates also frequently relied on unpublished data or posters, neither of which were subject to peer review, but were presented as valid scientific

evidence. These materials were aimed at hospitals (including St. Elizabeth), prescribers, patients, and payors.

9. Defendants used speakers' bureaus and programs to spread their deceptive messages.

332. In addition to making sales calls to Hospitals, the Manufacturing Associates' (with whom Defendants coordinated their activities) detailers also identified doctors to serve, for payment, on speakers' bureaus and to attend programs with speakers and meals paid for by the Manufacturing Associates.

333. These speaker programs and associated speaker trainings served three purposes: (1) to incentivize doctors to prescribe, or increase their prescriptions of, a particular drug; (2) an opportunity for doctors to be selected to attend forums at which the drug companies could further market to the speaker; and (3) an opportunity for the doctors to market to their peers.

334. Defendants and the unnamed associates used the techniques to place their misleading messages and falsehoods (also described above) before hospitals, doctors, patients, and health care payors. The intention and effect of this blitz of messaging was to increase opioid prescribing and placement on formularies regardless of the consequences for public health and safety.

E. The Defendants misrepresented their involvement in promoting opioids.

335. When accused of failing to monitor the distribution of hydrocodone and physicians prescribing excessive amounts, Defendants and the unnamed associates deliberately downplayed their role in driving the demand for prescription opioids and misrepresented their marketing strategies, particularly the work to change the standard of care surrounding opioid use generally.

336. Defendants and the unnamed associates misled the Hospitals, doctors, patients, healthcare payors, and even legislatures and law enforcement, ultimately delaying and frustrating the hope of any curtailment of the opioid crisis.

F. Defendants directly targeted hospitals.

337. From the beginning, hospitals were directly targeted by Defendants and the unnamed associates. Hospitals received mail and electronic communications from Defendants and the unnamed associates containing the misrepresentations described above.

338. Although this targeting is apparent in the revised JCAHO pain standards that Defendants orchestrated in order to promote opioid use, the targeting of hospitals began even earlier.

339. Internal documents from the 1995 "OxyContin Launch" orchestrated by Purdue and Abbott, coordinated with Defendants, identified (1) hospital pharmacists as among their "audience," (2) hospitals among their "institutional targets," (3) an objective of "[f]ormulary acceptance in 75% of hospitals for first twelve months," and (4) an objective of developing a "successful distribution program" to hospitals. Purdue used Abbott's sales force to market OxyContin directly to doctors working in hospitals.

340. The importance of targeting hospitals is illustrated by a study that "demonstrated that patients who receive an opiate prescription within 7 days of surgery are 44% more likely to still be using the medication one year after surgery than patients who do not receive an opioid prescription."[78]

[78] Cheryl Genord, et al., *Opioid Exit Plan: A Pharmacist's Role in Managing Acute Postoperative Pain*, 57 J. Am. Pharmacists Ass'n S92 (Jan. 2017), https://www.japha.org/article/S1544-3191(17)30016-X/fulltext (hereinafter *Opioid Exit Plan*).

341. This marketing push was successful and derived financial benefit to Defendants and the unnamed associates.[79]

342. Abbott assisted Purdue—two entities with whom Defendants coordinated their mutually beneficial activities—to expand the market for OxyContin (and their profits) by recruiting clinicians to participate in "studies" on expanded uses of OxyContin. This collaboration set the framework for future collaborations between Defendants and Associates in relation to their common purpose: profits.

G. Deceptive marketing caused excessive opioid use.

343. Pharmaceutical marketing and promotion effectively changed the habits of providers, prescribers and consumers.[80] Defendants and pharmaceutical associates would not spend large sums of money on direct and indirect marketing activities were it not effective. Defendants' and their Associates purposefully and intentionally planned and implemented promotional activities described, herein, to increase opioid prescriptions, opioid dependence and profits.

344. Defendants' and the unnamed associates' promotion directed at Hospitals and prescribers under the guise of education was designed to and, in fact, did influence Hospitals' and prescribers' decisions, and contributed to the opioid crisis.

345. Because marketing opioids to Hospitals and doctors was effective at making chronic opioid therapy a commonplace and often first-line treatment (by way of formularies and

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[79] *Id.*

[80] *See*, *e.g.*, *How Drug Marketing May Influence Prescriptions*, Nat'l Inst. of Health (May 23, 2017), https://www.nih.gov/news-events/nih-research-matters/how-drug-marketing-may-influence-prescriptions; *Spending on Consumer Advertising for Top-Selling Prescription Drugs in U.S. Favors Those with Low Added Benefit*, Johns Hopkins Bloomberg Sch. of Pub. Health (Feb. 7, 2023), https://publichealth.jhu.edu/2023/spending-on-consumer-advertising-for-top-selling-prescription-drugs-in-us-favors-those-with-low-added-benefit.

prescriptions), opioid prescription and usage rates have increased. Previously accounting for a small minority of opioid sales, today between 80 and 90% of opioids (measured by weight) are used for chronic pain.

346. The increasing number of opioid prescriptions has led to increased rates of opioid misuse because there is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[81] The opioid epidemic is thus "directly related to the increasingly widespread misuse of powerful opioid pain medications."[82]

347. The increasing number of opioid prescriptions has led to increased numbers of patients who, even if they are not abusing prescription opioids, have nevertheless become physiologically and/or psychologically dependent on them.[83] Such patients are more difficult, time-consuming, and resource-intensive to treat for any medical condition (not just those related to substance use) with which they present. This difference is caused by the patients' opioid use. These features of the OUD-patient cohort also cause staff burnout, empathy fatigue, staffing shortages, and security concerns.

348. The increase in prescriptions (driven by aggressive marketing) leads to increased rates of overdose.

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[81] Richard C. Dart, et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 New Eng. J. Med. 241 (2015), https://www.nejm.org/doi/pdf/10.1056/NEJMsa1406143.

[82] *See* Robert M. Califf, et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Engl. J. Med. 1480 (2016), https://www.nejm.org/doi/full/10.1056/NEJMsr1601307.

[83] *See* Emily O. Dumas & Gary M. Pollack, *Opioid Tolerance Development: A Pharmacokinetic/Pharmacodynamic Perspective*, 10 The AAPS Journal 537 (2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2628209/pdf/12248_2008_Article_9056.pdf ("Long-term use of opioids can be problematic due to the rapid development of profound tolerance to the analgesic effects . . . .").

349. The progression from prescription opioids to the use of illicit drugs, particularly heroin (and, more recently, fentanyl), is also well documented.[84]

350. Retrospective analysis reveals that by 2000, the false marketing campaign led to OxyContin sales 2.5 times higher in the targeted states than in the non-targeted states. Hence, the authors concluded that Purdue's false marketing had a direct effect on sales of OxyContin.[85] When looking at overdose deaths, the authors of that aforementioned study found low overdose death rates across the non-targeted states and much higher rates in the states where Purdue had concentrated its false marketing.

351. Based on their careful analysis, the authors concluded that the differences were attributable to Purdue's marketing.[86]

352. The study demonstrates that Defendants and the Manufacturing Associates spent billions of dollars developing shared marketing strategies for their drugs and did so for a strong return on their investment in the form of higher sales and profits.

V. DEFENDANTS UNLAWFULLY INFLATED THE SUPPLY OF OPIOIDS.

353. All Defendants and unnamed associates worked—with great success—toward their shared goal of creating a market for, and then filling/selling, far more opioids than could possibly have been medically appropriate or safe.

354. Defendants and the unnamed associates structured their contracts to give strong financial incentives to sell as many opioids as possible. Defendants benefitted from rebates or "chargebacks" that increased as the sales of pharmaceuticals increased. Joined by this powerful

[84] Theodore J. Cicero, et al., *The Changing Face of Heroin Use in The United States: A Retrospective Analysis of The Past 50 Years*, 71 J. Am. Med. Ass'n Psychiatry 821 (2014), https://jamanetwork.com/journals/jamapsychiatry/fullarticle/1874575.
[85] *Id.* at 20.
[86] *Id.* at 37 (emphasis added).

joint incentive to sell as many opioids as possible, Defendants cooperated to increase opioid sales and distribute and dispense opioids in violation of their CSA obligations.

355. Defendants created this illusion by repeatedly misleading the public and regulators into thinking that they had enacted safeguards, as they were required to do under the CSA.

356. Defendants also violated the CSA and various state laws identified, herein, by dispensing extremely large amounts of opioids from their retail pharmacy stores under circumstances in which diversion was highly likely, if not inevitable, while misleading law enforcement, regulators and the public that they were working to prevent diversion, and by, during the course of their distribution activities, failing to provide the required mechanisms, suspicious order monitoring, and other activities needed to comply with their distribution activities under the CSA.

357. Armed with knowledge of their own sales and shipments and industry-wide data Defendants knew or should have known that the quantity of opioids being distributed and dispensed far exceeded any possible medical need—even if the wider market for chronic pain had been entirely legitimate (which it was not). Defendants knew or should have known that a significant number of opioids were being diverted from legitimate medical uses. Opioid shipments continue to be far greater than medically justified.

358. Sources of information placing Defendants on notice that the volume of opioids they were shipping must have been excessive include, without limitation:

a. Detailed transaction-level data on the sale, distribution, and dispensing of opioids, which can be broken down by zip code, prescriber, and pharmacy, and includes the volume of opioids, dose, and the distribution and dispensing of other controlled and non-controlled substances; and

b. Knowledge of the detailed data from the Distributor Associates concerning volume of their own transactions, quotas and sales, and the probability of diversion.

359. The Distributor Associates distributed eye-popping quantities of opioids into Kentucky. As measured in milligram morphine equivalents (MMEs), between 2006 and 2019:

- ABDC – 7,835,172,159 MMEs
- Cardinal – 6,574,649,880 MMEs
- McKesson – 5,220,885,843 MMEs
- Walgreens – 2,128,334,118 MMEs
- Walmart – 1,650,070,130 MMEs
- CVS – 461,437,090 MMEs

360. The increased supply of opioids engineered by the Opioid Promotion Enterprise caused the exaggerated use of opioids that damaged hospitals like St. Elizabeth. By working to ensure that far more opioids were available in the community than could ever have been needed for legitimate medical purposes, by being the last-mile mule for the cartel to place the pills in the hands of the patient, and by thwarting red-flag systems, including with incentive payments for speed-filling, Defendants provided a necessary condition for the dangerous increased use. In turn, Hospitals, like St. Elizabeth, experienced increased OUD patient encounters and the attendant losses described, above. Defendants also knowingly deprived their pharmacists of the data and information to perform necessary corresponding responsibility, purposefully and knowingly violating and avoiding CSA requirements, toward their mutual financial benefit.

A. Distributors have duties under the CSA.

361. The CSA defines a "distributor" as a person or an entity that delivers (other than by administering or dispensing) a controlled substance. The CSA defines "delivery" as the "actual, constructive, or attempted transfer of a controlled substance…." *See* 21 U.S.C. §§ 802(8), (11). Defendants were at relevant times "distributors" under the CSA.

362. Many pharmacies obtain controlled substances from independent distributors, but the National Retail Pharmacies served as their own drug distributors until 2014 (CVS, Walgreens) and 2018 (Walmart).

363. Distributors of controlled substances are required by the CSA to register with DEA and to maintain effective controls against the diversion of controlled substances for illegitimate uses. *See* 21 U.S.C. § 823(b)(1) (requiring the Attorney General, in registering a distributor, to consider whether the distributor has shown "maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."). The Attorney General has delegated this authority to DEA. *See* 28 C.F.R. § 0.100; 21 C.F.R. § 1300.01.

364. Under the CSA, it is unlawful for a distributor to distribute a controlled substance "[e]xcept as authorized by this subchapter." 21 U.S.C. § 841(a) ("Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally (1) to . . . distribute . . . a controlled substance").

365. The CSA provides the Attorney General broad authority to "promulgate and enforce any rules, regulations and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter." 21 U.S.C. § 871(b); *see also* 21 U.S.C. § 821. The Attorney General has issued numerous regulations establishing an extensive regulatory regime. *See* 21 C.F.R. §§ 1300.01-1321.01.

366. The Attorney General has long required distributors to design and operate a system to detect suspicious orders of controlled substances, and to report those orders to DEA. *See* 21 C.F.R. § 1301.74(b). This provision reads, in full:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field

> Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

367. In other words, orders that are unusual in one of those three ways—size, pattern, or frequency—are deemed "suspicious orders," and a distributor must detect and report them to DEA. "Suspicious orders," however, are not limited to those three categories, which are non-exclusive.

368. If a distributor fails to detect and report a suspicious order, it violates the law. Under 21 U.S.C. § 843(a)(4)(A), it is unlawful for any person, including a distributor, to "knowingly or intentionally . . . furnish false or fraudulent information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II . . . ."

369. Defendants have a duty to report suspicious orders in order to prevent diversion. In addition to reporting all suspicious orders, as has been confirmed by courts and reiterated by the DEA, Defendants must also stop shipment on any order which is flagged as suspicious; they may only ship orders that were flagged as suspicious if, after conducting due diligence, the recipient determines that the order is not likely to be diverted into illegal channels.[87]

B. Pharmacies have duties under the CSA.

370. Defendants also operated pharmacies that "dispensed" controlled substances. "Dispensing" means delivering a controlled substance to an end user pursuant to a physician's prescription. *See* 21 U.S.C. § 802(10); 21 C.F.R. §§ 1300.01, 1306.03(a).

371. The CSA designates pharmacies as "practitioners" that are permitted to handle controlled substances "in the course of professional practice or research." *See* 21 U.S.C. § 802(21).

[87] *See* Southwood Pharm., 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharm., Inc. v. Drug Enforcement Admin.*, 861 F.3d 206 (D.C. Cir. 2017).

372. Pharmacies that wish to dispense controlled substances are required under the CSA to register with the Attorney General. *See* 21 U.S.C. § 823(f). The Attorney General has delegated this authority to DEA. *See* 28 C.F.R. § 0.100; 21 C.F.R. § 1300.01.

373. DEA reviews applications for registration (and renewals of registration) by pharmacies and, where necessary, pursues revocations of registrations. In deciding whether to issue or deny a registration for a pharmacy, DEA considers various factors, including whether the applicant for a registration has complied with the laws relating to controlled substances and its other conduct related to public health and safety. *See* 21 U.S.C. § 823(f).

374. Pharmacists who dispense controlled substance as an "agent or employee" of a pharmacy registered with DEA need not register individually with DEA. *See* 21 U.S.C. §§ 822(c)(1), 823(f).

375. In general, the CSA prohibits pharmacies from dispensing most controlled substances without a "prescription issued by a practitioner." *See* 21 U.S.C. § 829(a)–(b).

376. The CSA makes it unlawful "for any person … to … dispense a controlled substance in violation of section 829." 21 U.S.C. § 842(a)(1).

377. The Attorney General has promulgated, in 21 C.F.R. Part 1306 ("Prescriptions"), rules for when prescriptions may be filled pursuant to a prescription in accordance with 21 U.S.C. § 829. *See* 21 C.F.R. § 1306.01 ("Rules governing the issuance, filling, and filing of prescriptions pursuant to [21 U.S.C. § 829] are set forth generally in this section and specifically by the sections of this part.").

378. As relevant here, Part 1306 sets forth three rules pharmacies must follow when dispensing controlled substances. For each controlled-substance prescription, a pharmacist must (1) determine that the prescription was issued by a medical practitioner adhering to the usual course

of his or her professional practice, (2) determine that the prescription is for a legitimate medical purpose, and (3) in filling the prescription, adhere to the usual course of his or her own professional pharmacy practice.

379. The National Retail Pharmacies were required to adhere to these three requirements in their roles as pharmacies dispensing controlled substances.

380. 21 C.F.R. § 1306.04(a) defines certain requirements for a controlled-substance prescription to be valid or "effective" and imposes obligations on both the medical practitioner who issues the prescription and the person who fills the prescription.

381. To be valid or effective, a prescription for a controlled substance must meet two requirements. First, it must be issued by a medical practitioner acting in the usual course of his professional practice. *See* § 1306.04(a). For example, a prescription is not issued for a legitimate medical purpose if it is issued or sought for nonmedical use or abuse by a patient.

382. While section 1306.04(a) imposes a responsibility on prescribers (medical practitioners) to issue valid prescriptions, it also imposes a "corresponding responsibility" on the pharmacist who fills the prescription to independently determine that the prescription is meets these requirements. *See* § 1306.04(a). The pharmacist's corresponding responsibility includes identifying and attempting to resolve red flags, to document the resolution if the red flag is resolved, and to refuse to fill the prescription if the red flag is not resolved.

383. A third relevant rule that a pharmacist must follow in filling prescriptions for controlled substances is found in section 1306.06, which requires that the pharmacist's conduct must adhere to the usual course of his or her professional practice as a pharmacist. *See* 21 C.F.R. § 1306.06.

384. Pharmacists are professionals who must be licensed by the states in which they practice. A basic licensing requirement common across states is a Doctor of Pharmacy ("Pharm.D.") degree.

385. Pharmacists are trained in the role they play in preventing prescription drug misuse and diversion. For example, the Accreditation Council for Pharmacy Education, which publishes accreditation standards and guidelines for Pharm.D. programs, requires that the Pharm.D. curriculum includes a discussion of the laws regulating pharmacy practice and the mitigation of drug misuse and diversion.

386. In evaluating the validity of a controlled-substance prescription, pharmacists cannot rely exclusively on the mere fact that it was issued by a medical practitioner. A pharmacist must consider any signs that a prescription may be invalid or that the controlled substances may be misused.

387. Pharmacists call these signs of invalidity "red flags." Red flags may arise based on the prescriber who issued the prescription (e.g., where a prescriber issues many more prescriptions of opioids for higher quantities than do comparable prescribers), the prescription itself (e.g., where the combination of drugs prescribed is frequently sought by individuals known to misuse prescription drugs), or the individual presenting the prescription (e.g., where a patient repeatedly seeks early refills).

388. One well-recognized key professional responsibilities of a pharmacist, when presented with a prescription for controlled substances, is to identify and resolve any "red flags" before filling the prescription.

389. This responsibility also has been recognized as an important safeguard against the misuse of controlled substances. For example, in 2014, the National Association of Boards of

Pharmacy released a video called "Red Flags," which observed that "by recognizing red flags to help establish the validity of a prescription, the pharmacist becomes the last line of defense in preventing misuse." The video states, "problem prescriptions can often be identified by using common sense, practicing good pharmacy, and looking for red flags that suggest the prescription may not be legitimate."

390. When a pharmacist identifies red flags but can resolve them, the pharmacist has an additional professional responsibility: to document the resolution of the red flags. In other words, pharmacists were trained that, when presented with a controlled-substance prescription bearing a significant red flag, they needed—as part of the usual course of professional pharmacy practice—to investigate and either (a) resolve the red flag before dispensing *and* document the resolution, or (b) refuse to fill the prescription. The documentation ensures that the information about the red flag and its resolution is available for future reference, and the absence of documentation can indicate that the pharmacist did not successfully resolve the red flag.

391. Because this obligation—to identify any red flags relating to a prescription for controlled substances, to resolve them before filling the prescription, and to document any resolution of red flags—is a well-recognized responsibility of a pharmacist in the professional practice of pharmacy, failing to fulfill this responsibility is a violation of 21 C.F.R. § 1306.06, which requires that a pharmacist's conduct, when filling controlled-substance prescriptions, must adhere to the usual course of his or her professional practice as a pharmacist.

392. The CSA makes it unlawful "for any person … subject to the requirements of Part C [21 U.S.C. §§ 821–32] to distribute or dispense a controlled substance in violation of section 829." 21 U.S.C. § 842(a)(1) (emphasis added). A person dispensing controlled substances not in

compliance with any of the three requirements identified above violates 21 U.S.C. § 829 and thus 21 U.SC. § 842(a)(1).

393. When a corporation's agents or employees violate the rules for dispensing controlled substances, the corporate entity may be held liable for the civil penalty. Corporations must comply with the CSA when they engage in activities covered by the CSA or its implementing regulations, such as operating a pharmacy that dispenses controlled substances. *See* 21 U.S.C. §§ 822(b), 823(f). While the CSA, in 21 U.S.C. § 842(a)(1) and (c)(1), makes a "person" liable for civil penalties, a corporate entity may be the "person" that fills prescriptions through its agents, as the CSA's regulations expressly define "person" to include corporations. *See* 21 C.F.R. §§ 1300.01, 1306.02.

C. Defendants have duties under Kentucky law.

394. The Defendants also had legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids under Kentucky law.

395. Pursuant to KRS § 218A.170(8), Defendants must adhere to Kentucky's controlled substances law in the sale of controlled substances. *See* KRS § 218A.170(8) ("All sales and distributions shall be in accordance with KRS § 218A.200 and the federal controlled substances laws, including the requirements governing the use of order forms."). Thus, all Defendants have a duty to report suspicious orders in order to prevent diversion.[88] Pharmacies are required to ensure that opioid prescriptions they fill are written for a legitimate patient for a legitimate medical need.

[88] Federal requirements impose a non-delegable duty upon registrants to design and operate a system to disclose to the registrant suspicious orders of controlled substances. "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency" 21 C.F.R. § 1301.74(b).

See KRS § 218A.180(3)(a) ("[T]o be valid, a prescription for a controlled substance shall be issued only for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice[.]").

396. Further, "[m]anufacturers and wholesalers shall keep records of all controlled substances compounded, mixed, cultivated, grown, or by any other process produced or prepared, and of all controlled substances received and disposed of by them." KRS § 218A.200(2). "The record of controlled substances received shall in every case show the date of receipt, the name and address of the person from whom received, and the kind and quantity of drugs received. The record of all controlled substances sold, administered, dispensed, or otherwise disposed of, shall show the date of selling, administering, or dispensing, the name and address of the person to whom, or for whose use, or the owner and species of animal for which the drugs were sold, administered, or dispensed, and the kind and quantity" KRS § 218A.200(4).

397. Each Defendant's actions were in violation of Chapter 218A of the Kentucky Revised Statutes, as set out above, and also including § 218A.1404(3), which forbids unlawful distribution of controlled substances; § 218A.1404(1), which forbids the trafficking of controlled substances; and, KRS §§ 506.040 and 218A.1402, which forbid criminal drug conspiracies; and KRS § 218A.1405, which forbids receipt of income from trafficking and utilizing that income to operate a commercial enterprise.

398. Defendants breached these duties. Kentucky state law requires that a "manufacturer, distributor, or wholesaler" must comply with "KRS § 218A.200 and the federal controlled substances laws." KRS § 218A.170.

399. Pursuant to KRS § 218A.200, Defendants, as distributors and retail pharmacies, are required to ensure that opioid prescriptions filled by them are written for a legitimate patient for a

legitimate medical need in the usual course of practice for the prescriber. *See* KRS § 218A.180(3)(a). In addition, "[e]ach pharmacy shall comply with KRS § 218A.202," which requires that "Every practitioner or pharmacy which dispenses a controlled substance to a person in Kentucky, or to a person at an address in Kentucky, shall report to the Cabinet for Health and Family Services the data required by this section, which includes the reporting of any Schedule II controlled substance dispensed at a facility licensed by the cabinet and a Schedule II through Schedule V controlled substance regardless of dosage when dispensed by the emergency department of a hospital to an emergency department patient." KRS § 315.035(7); KRS § 218A.202(3). Because Defendants are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

D. Defendants failed to comply with their CSA obligations to identify, report, and halt suspicious orders.

400. Each Defendant, through coordinated conduct with the unnamed associates and each other Defendant, and as a distributor of controlled substances and retail pharmacy, through concerted and coordinated activities, violated the requirements under the CSA to prevent diversion by operating a program that would identify, report, and not ship suspicious orders of prescription opioids without adequate investigation.

1. Walgreens

401. As stated herein and through other measures to be demonstrated at trial, through concerted and coordinated, conspired activities with the other Defendants and unnamed associates, toward their mutual financial benefit, Walgreens conspired and acted to avoid their CSA obligations as a distributor of prescription opioids for their financial benefit and mutual financial benefit with Defendants. Walgreens's corporate officers not only turned a blind eye; they also provided pharmacists with incentives through a bonus program that compensated them based on

the number of prescriptions filled at the pharmacy. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens's attitude that profit outweighed compliance with drug laws or the health of communities.[89]

402. Walgreens admitted that its Suspicious Order Monitoring Program failed to halt suspicious order because it "would continue to send additional product to [a Walgreens store] without limit or review which made possible the runaway growth of dispensing products like oxycodone."

403. Walgreens's program from 2010 to 2012 had significant gaps or loopholes which caused Walgreens to continue to provide its stores with suspicious quantities of controlled substances, including the following:

404. Walgreens continued to neglect to incorporate a store's orders of controlled substances from outside distributors into the determination of whether a given order was suspicious. This allowed stores to circumvent the effect of orders being cut by Walgreens distribution centers because stores could simply place the cut portion of the order with an outside distributor.

405. Walgreens allowed interstoring (obtaining drugs from other Walgreens stores) of controlled substances until April 2013 but did not account for interstoring when identifying suspicious orders.

[89] Order to Show Cause & Immediate Suspension of Registration, *In re Walgreens Co.* (Drug Enf't Admin. Sept. 13, 2012) (hereinafter "2012 Walgreens ISO"); Jenn Abelson, et al., *At Height of Crisis, Walgreens Handled Nearly One in Five of the Most Addictive Opioids*, Wash. Post (Nov. 7, 2019), https://www.washingtonpost.com/investigations/2019/11/07/height-crisis-walgreens-handled-nearly-one-five-most-addictive-opioids/.

406. Walgreens's SOM algorithm only considered 13 weeks of sales data and would recalibrate the thresholds if there was a gradual increase in sales. Only a sudden spike in sales would result in orders getting cut.

407. In addition to their regular periodic orders for controlled substances from the Walgreens distribution centers, Walgreens stores were permitted to place ad hoc "PDQ" ("pretty darn quick") orders for controlled substances outside of their normal order days. The limits and automatic reductions Walgreens placed on stores' orders to distribution centers did not apply to PDQ orders, such that a store could, for instance, hit its weekly limit for a particular controlled substance and then place daily PDQ orders for the same drug, resulting in total order amounts far exceeding the monthly cumulative order limits put in place by Walgreens's SOM program. Walgreens did not remove oxycodone from PDQ ability until October 2012; other Schedule II controlled substances were not removed from PDQ until even later.

408. Walgreens only examined its stores individually rather than comparing them to one another. The result was that a store that historically had a pattern of excessively large orders could continue making excessively large orders.

409. Walgreens had the ability to remove entire stores and products from SOM review.

410. Even when Walgreens began cutting orders over a certain limit, stores could simply "call the DC" to obtain a "manual work around" the purported limit. The distribution centers did not have the ability to evaluate the information necessary to determine the propriety of any such overrides.

411. One example of the sorts of information that was available and considered, but not acted upon, is found in emails from January 10–11, 2011 between a Walgreens DC employee and Barbara Martin, identified by Walgreens as being one of two employees primarily responsible for

performing due diligence on suspicious orders in the 2009–2012 time period under the new SOM system. The DC employee noted "several stores that are ordering huge quantities of 682971 [30 mg oxycodone] on a regular basis," and with respect to a single store, "we have shipped them 3271 bottles [of 30 mg oxycodone] between 12/1/10 and 1/10/11. I don't know how they can even house this many bottles to be honest. How do we go about checking the validity of these orders?" Ms. Martin stated "I have no idea where these stores are getting this type of volume… ." Even though questions had been raised about this store ordering volume in January 2011, the very next month, Walgreens filled and shipped orders totaling another 285,800 dosage units of 30-milligram oxycodone to the same pharmacy.[90]

412. Of the orders that were the subject of these email exchanges, DEA specifically found that "[b]ased on the evidence available to DEA, none of these orders were reported to DEA as suspicious and all appear to have been shipped, without any further due diligence to verify their legitimacy."[91]

413. Walgreens also used its substantial market share to aggressively (and often successfully) lobby its distributors to increasingly raise ordering thresholds for its pharmacies and worked to have suspicious orders placed by its pharmacies filled by not reported to DEA.

2. CVS

414. As stated herein and through other measures to be demonstrated at trial, through concerted and coordinated, conspired activities with the other Defendants and unnamed associates, toward their mutual financial benefit, CVS conspired and acted to avoid their CSA obligations as a distributor of prescription opioids for their financial benefit and mutual financial benefit with

[90] *See* 2012 Walgreens ISO, *supra*.
[91] *Id.*

Defendants. CVS failed to maintain an effective suspicious order monitoring system or to complete necessary due diligence.

415. Before 2009, CVS did not have a Suspicious Order Monitoring ("SOM") system. Instead, CVS relied on the gut instincts of "Pickers and Packers" of the drugs in the distribution center to identify "really big" orders that they believed were simply too large.

416. As of November 2011, CVS had a "CVS DEA compliance coordinator" in name only. A former CVS employee who held the position at that time has said that this was only "for reference in SOPs," not her real job. For "personnel purposes," she was never considered the CVS DEA compliance coordinator. Moreover, she had nothing to do with suspicious order monitoring, other than "updating the SOP with what was provided for the program."

417. CVS failed to remedy fatal flaws in the system it slowly developed. In 2009, CVS began using a computer algorithm that flagged potentially suspicious orders needing additional investigation. But this program was still deficient. It monitored by drug, not by active ingredient, meaning that changes in a drug's description or name caused historical data, necessary for valid calculations, to be lost. It also failed to consider orders from distributors outside of CVS.

418. Meanwhile, even if orders were flagged, CVS did not conduct appropriate due diligence on them. Even though the SOM program would identify between 200 and 500 suspicious orders a day, the CVS employee would only have time to do a "deep dive" on 5-6 orders per day.

419. As late as July 2013, internal e-mails reflect that CVS's primary tool for investigations used stale data that made any analysis, "for the most part, irrelevant and pointless."

420. Not until mid- to late 2014 did CVS fully implement the new SOM system. That same year, all CVS distribution centers stopped distributing Schedule II opioids at the wholesale level.

421. CVS worked with other defendants to avoid monitoring and reporting suspicious orders. CVS understood that for Cardinal and McKesson to meet their due-diligence obligations under the CSA, they would need access to CVS's dispensing information. CVS refused to provide dispensing information about doctors or patients unless it was requested by DEA.

422. Prior to 2013, Cardinal and McKesson performed due diligence differently for CVS than for other pharmacies. Instead of distributors contacting or visiting CVS stores, as with other pharmacies, they contacted CVS's loss-prevention offices at corporate headquarters. This meant that CVS controlled all "due diligence investigations" of its opioid orders. CVS prevented distributors from independently determining appropriate order thresholds for opioids at CVS stores, reserving the right to adjust threshold quantities and percentages to values CVS deemed appropriate.

3. Walmart

423. As stated herein and through other measures to be demonstrated at trial, through concerted and coordinated, conspired activities with the other Defendants and unnamed associates, toward their mutual financial benefit, Walmart conspired and acted to avoid their CSA obligations as a distributor of prescription opioids for their financial benefit and mutual financial benefit with Defendants. From 2000 to approximately May 2018, Walmart self-distributed tens of millions of shipments of controlled substances to Walmart-branded and Sam's Club-branded pharmacies. In this role, Walmart violated the CSA.

424. Walmart had access to a wealth of information and data such that it could readily have designed a system to adequately detect suspicious orders. Walmart's self-distribution to its own pharmacies gave it extensive knowledge and data about dispensing patterns and orders. Walmart also had information on the millions of orders for controlled substances its pharmacies placed with—and received from—independent distributors.

425. For years, Walmart knew of significant defects in its policies and procedures for detecting and reporting suspicious orders but failed to fix them.

426. Prior to August 2015, Walmart had a rudimentary suspicious-order monitoring system that failed to adequately detect and report suspicious orders. This system failed to detect and report orders of unusual size, unusual frequency, or unusual pattern. At the same time, Walmart ignored signs of diversion from its own pharmacies, such as concerns expressed by pharmacists to compliance personnel about prescriptions written by "pill mill" prescribers and illegal diversion occurring inside Walmart stores. Walmart also failed to adequately staff and train its compliance personnel and shipped flagged orders before compliance personnel could examine them. Walmart routinely failed to investigate flagged "orders of interest" and report any order that Walmart was unable to clear to DEA. Walmart often failed to document its evaluation of flagged orders, which deprived it of crucial information needed to assess subsequent orders.

427. From August 2015 through November 2017, Walmart adopted a modified system for detecting and reporting suspicious orders. Despite these modifications, many of the same flaws remained. Walmart continued to fail to report unusually large orders. Walmart set hard limits for pharmacies that had already placed suspicious orders only to then disregard those hard limits and ship suspicious quantities of controlled substances.

428. Walmart's SOM was so deficient that it failed to report at least hundreds of thousands of suspicious orders. From June 26, 2013, to November 29, 2017, Walmart sent its pharmacies 15.2 million orders of Schedule II controlled substances and Schedule III narcotics. In that time, it reported only 204 suspicious orders. By comparison, McKesson, when receiving

orders from Walmart pharmacies, reported more than 13,000 suspicious orders in the same period.[92]

429. This failure to detect and report suspicious orders deprived Walmart of the opportunity to timely address its unlawful conduct, which was contributing to the opioid epidemic.

4. Other Entities

430. Other entities, including Kroger and Albertsons, acted in concert with Defendants and the unnamed associates to conspire and avoid their CSA obligations for their financial benefit and mutual financial benefit with Defendants.

E. The National Retail Pharmacies dispensed opioids in violation of the CSA.

1. Walgreens

431. Walgreens sold massive quantities of opioids by failing to maintain effective controls against misuse and diversion and taking affirmative steps to undermine its own opioid diversion controls and those of others.

432. Walgreens designed anti-diversion compliance programs, including Suspicious Order Monitoring and Good Faith Dispensing, that had significant flaws, were designed to minimize their impact on opioid sales to its stores, and yielded to Walgreens's higher priority to generate profit. These compliance programs and policies were a low corporate priority, understaffed, fundamentally unsound, applied inconsistently, or completely ignored, with these failures purposeful to avoid their CSA obligations and to provide Walgreens financial benefit in coordination with their activities with the other Defendants.

[92] Complaint, *United States v. Walmart Inc.*, No. 20-1744-CFC (D. Del. filed Dec. 22, 2020), https://www.justice.gov/opa/press-release/file/1347906/download (hereinafter "Walmart DOJ Complaint").

433. According to DEA, Walgreens's pharmacies "filled customer prescriptions that they knew or should have known were not for legitimate medical use."[93] Walgreens pressured pharmacists to fill an increasing volume of opioid prescriptions, even if it meant filling ones that the pharmacist had concerns about, and failed to provide the pharmacists the data and information needed to comply with the CSA.

434. Walgreens compensated its pharmacists based on the volume of controlled substances they filled, including CII opioids. It told its pharmacists that concerns about whether a prescription should be dispensed do not "relieve you from trying to attain the numbers that have been set for you."

435. For years, Walgreens did not have any method to determine if its pharmacists were complying with its dispensing policies and no process for disciplining noncompliant pharmacists. Walgreens offered no employee training regarding controlled substance dispensing or detecting red flags for opioid misuse and diversion, even after it implemented policies regarding such.

436. Walgreens's determination to bury evidence of noncompliance in the service of profit goals has continued. When a Walgreens consultant interviewed Walgreens pharmacy employees, they drafted a report finding that employees "sometimes skirted or completely ignored" proper procedures to meet corporate metrics and committed "errors resulting from stress." The consultants reported that they "heard multiple reports of improper behavior" that were "largely attributed to the desire" to meet a corporate metric known as "promise time," which ensures that patients get prescriptions filled within a set amount of time. Upon reviewing a draft of the report, senior leaders at Walgreens directed the consultants to remove some of the damaging

[93] *Walgreens Agrees to Pay a Record Settlement of $80 Million for Civil Penalties Under the Controlled Substances Act*, U.S. Dep't Just. (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled (hereinafter *Walgreens Agrees to Pay*).

findings, which the consultant company ultimately did, even though the consultant's employees stated requests to remove information from slides conflicted with their business ethics. At around this same time, Walgreens awarded the consultant company a $1.5 billion contract.[94]

437. DEA found evidence that Walgreens had a corporate policy encouraging increased sales of oxycodone:

> In July 2010, Walgreens's corporate headquarters conducted an analysis of oxycodone dispensing for the prior month at its Florida retail pharmacies and produced an 11-page spreadsheet, ranking all Florida stores by the number of oxycodone prescriptions dispensed in June. The spreadsheet was sent to Walgreens's market pharmacy supervisors in Florida on July 29, 2010, with the admonition that they "*look at stores on the bottom end . . . . We need to make sure we aren't turning legitimate scripts away. Please reinforce*." A corporate market director of pharmacy operations did reinforce this message to Florida market pharmacy supervisors, highlighting that their "*busiest store in Florida*" was filling almost 18 oxycodone prescriptions per day, yet "*We also have stores doing about 1 a day. Are we turning away good customers?*"[95]

438. In 2011, a Walgreens project to "Increase Rx Sales and prescription Counts" instructed pharmacies to "improve C2 business," i.e., dispense more Schedule II controlled substances. This focus on increasing controlled-substance dispensing, including opioids, continued even after DEA investigation and $80 million fine. For example, in 2014, the Rx Integrity department created a "Pharmacist Controlled Substance Dispensing Opportunities" tool to "identify pharmacists that are dispensing a low rate of controlled substances" and help pharmacists "feel more comfortable in filling controlled substances," specifically focusing on pharmacists dispensing low rates of opioids like "hydromorphone, oxycodone, methadone . . . hydrocodone," and the cocktail drugs comprising the rest of the "holy trinity", such as "carisoprodol . . . [and] alprazolam."

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[94] Ellen Gabler, *At Walgreens, Complaints of Medication Errors Go Missing*, N.Y. Times (Feb. 21, 2020), https://www.nytimes.com/2020/02/21/health/pharmacies-prescription-errors.html.
[95] 2012 Walgreens ISO, *supra*.

439. Walgreens sold huge amounts of dangerous combinations of controlled substances, despite recommendations from its Director of Rx Integrity, who stated, "there is no[] clinical proof that a cocktail works other than to potentiate [i.e., enhance] the opiate." Despite internal warnings not to fill cocktail prescriptions because DEA considered them a red flag, no restrictions were put in place regarding the dispensing of these dangerous combinations.

440. Walgreens refused to allow pharmacies to ban filling prescriptions for controlled substances written by certain healthcare providers, even if there was verifiable evidence that the provider was operating an illegal pill mill. In fact, Walgreen regularly continued to fill prescriptions for such prescribers, long after evidence (such as having worked at clinics shut down by law enforcement) was already available.

441. Walgreens filled prescriptions for controlled substances that were missing essential required information, such as the prescriber's DEA number.

442. Walgreens ignored evidence of patient doctor shopping and instead filled overlapping prescriptions from different doctors for the same controlled substances.

2. CVS

443. CVS sold massive quantities of opioids by failing to maintain effective controls against misuse and diversion and taking affirmative steps to undermine its own opioid diversion controls and those of others. All of the actions described herein reflect their coordinated scheme and conspiracy with the other Defendants to obtain a mutual financial benefit from their acts and omissions.

444. CVS lacked meaningful policies and procedures to guide its pharmacy staff in maintaining effective controls against diversion, even as they evolved over time. Not until 2012 did CVS create guidelines explaining in more detail the "red flags" or cautionary signals that CVS pharmacists should be on the lookout for to prevent diversion and to uphold their corresponding

responsibilities to ensure that all dispensed controlled substances are issued for a legitimate medical purpose. Even so, CVS's conduct and the volume it dispensed thereafter indicate that its policies were not applied.

445. CVS's performance metrics pressured pharmacists to put profits ahead of safety. CVS's metrics system lacked any measurement for pharmacy accuracy or customer safety. They did, however, prioritize speed and volume, including by requiring pharmacists to meet wait- or fill-time expectations. CVS also failed and refused to provide its pharmacists with the data and information necessary to help the pharmacists comply with the CSA requirements, though CVS had this information. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. Opioid prescriptions were even included in the volume goals until 2013, and after that time, the pressure from the metrics' focus on profitability remained. These policies remained in place even as the epidemic raged. Even in 2020, pharmacists described CVS as the "most aggressive chain in imposing performance metrics."[96]

446. Under these circumstances, a pharmacist is likely to be too rushed to check for red flags for diversion, such as prescription "cocktails" or other combinations of highly misused drugs.

447. DEA explained these red flags for diversion to CVS in December 2010 at a meeting with CVS's representatives and counsel. DEA identified "red flags . . . that a pharmacy should be familiar with in order to carry out its corresponding responsibility to ensure that the controlled substances are dispensed for a legitimate medical purpose."[97]

448. Examples of red flags that DEA identified during its meeting with CVS include:

a. Many customers receiving the same combination of prescriptions (i.e., oxycodone and alprazolam)

[96] *See* Ellen Gabler, *How Chaos at Pharmacies Is Putting Patients at Risk*, N.Y. Times, (Jan. 31, 2020), https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html.
[97] Declaration of Joe Rannazzisi in *Holiday CVS, L.L.C. v. Holder*, 839 F. Supp.2d 145 (D.D.C. 2012).

b. Many customers receiving the same strength of controlled substances (i.e., 30 milligrams of oxycodone with 15 milligrams of oxycodone and 2 milligrams of alprazolam)

c. Many customers paying cash for their prescriptions; many customers with the same diagnosis codes written on their prescriptions (i.e., back pain, lower lumbar, neck pain or knee pain)

d. Individuals driving long distances to visit physicians and/or to fill prescriptions.[98]

449. CVS's lack of adequate policies and procedures to protect against diversion and its failure to enforce policies because of its focus on speed resulted in CVS pharmacies drastically oversupplying their communities.

450. These problems and the lack of support from CVS for its individual stores are not a matter of the distant past. For example, a CVS pharmacist emailed a district manager in 2020:

> There is a huge CII problem in this area and we are grossly under resourced to deal with it. I am getting people from Spring Hill, Brooksville, east side of Tampa, and deep from Saint Pete bringing everything from pain meds to ERX Adderall. We are legitimately overrun and not able to deal with it. From 55146 to 709 we cannot deal with it. It is a complete free-for-all and every RPh seems to be in survival mode. We need corporate help and this needs to be escalated.
>
> . . .
>
> Many of these scripts shouldn't be filled. Walgreens, Publix, Walmart, Winn-Dixie are all turning them away, too. They come to us to fill them, but take the non-controls to mail order and Sam's Club or Publix. The Walgreens across the street, per customers, has stopped filling just controls for their patients. Guess what, they are coming to us . . . You want your stores to succeed, this needs to be addressed.

3. Walmart

451. Walmart sold massive quantities of opioids by failing to maintain effective controls against misuse and diversion and taking affirmative steps to undermine its own opioid diversion controls and those of others, with these and other activities described herein aimed to continue

[98] *Id.*

their coordination and conspiracy with the other Defendants to commit these unlawful acts toward their mutual financial benefit.

452. In Silver City, Kentucky, a single Walmart pharmacy dispensed 8 million opioid pills between 2006 and 2018—732 pills for each and every person in Silver City during that time.

453. Walmart impeded its pharmacists' ability to comply with legal requirements for dispensing controlled substances.

454. Walmart managers pressured pharmacists to fill prescriptions as quickly as possible.

455. Walmart's compliance unit chose not to give its pharmacists the information and authority it knew they needed to comply with its rules. Consistent with the CSA, Walmart's own policy required pharmacists to identify and resolve red flags and to document any resolution of red flags. After Walmart was accused of dispensing violations, it committed to adopting a nationwide compliance program to identify red flags and prevent diversion. While Walmart's compliance unit did compile red-flag information, it chose not to disseminate that information to pharmacists.

456. Meanwhile, Walmart forbade its pharmacists from refusing to fill, as a blanket matter, all prescriptions issued by pill-mill prescribers. A 2011 document from Walmart Regulatory Affairs regarding the "Proper Prescriber-Patient Relationship" stated: "Blanket refusals of prescriptions are not allowed. A pharmacist must make an individual assessment of each prescription and determine that it was not issued based on a valid prescriber-patient relationship or a valid medical reason before refusing to fill."[99] Walmart only began to allow blanket refusals to fill in 2017.

[99] Jesse Eisinger & James Bandler, *Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment.*, ProPublica, (Mar. 25, 2020), https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment (hereinafter, "Eisinger & Bandler").

457. Because Walmart refused until 2017 to allow blanket refusals, Walmart created a situation in which inappropriate dispensing of opioids was inevitable. Walmart pharmacists could not simultaneously comply with Walmart's demand to fill prescriptions quickly and its demand that each prescription from a pill-mill doctor be separately rejected and documented on a refusal-to-fill form.[100] Walmart also failed and/or refused to provide its pharmacists with the information and data to assist their compliance with the CSA obligations.

458. Even after Walmart pharmacists identified pill-mill prescribers who were issuing invalid prescriptions, Walmart kept filling their prescriptions. For instance, despite individual Walmart stores refusing to fill his prescriptions, Walmart pharmacies in states across the country, including in Alabama, Arizona, Arkansas, Colorado, Connecticut, Delaware, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, and Wisconsin, filled opioid prescriptions from one Miami, Florida physician, R.M. Walmart filled more than 300 controlled-substance prescriptions written by R.M. from June 2015 through May 2016. R.M. was indicted by a federal grand jury in November 2015 for violations of federal controlled-substance laws. Walmart therefore continued to fill prescriptions for controlled substances written by R.M. six months after he was indicted.[101]

459. Walmart also filled many invalid prescriptions that were the same or similar to other prescriptions Walmart pharmacists had previously identified as invalid for the same customer.

460. In May 2018, the U.S. Attorney for the Eastern District of Texas informed Walmart that it would bring a criminal indictment against Walmart for its role in the opioid epidemic. Facing

[100] Walmart DOJ Complaint, *supra*.
[101] *Id.*

the threat of criminal charges, Walmart amended its pharmacy operating manual. The new manual detailed a number of prescriber and patient red flags. After taking this step, Walmart issued a press release titled, "Walmart Introduced Additional Measures to Help Curb Opioid Abuse And Misuse." The press release promised that within the next sixty days, Walmart would restrict initial acute opioid prescriptions to no more than a seven-day supply. Walmart also promised to require e-prescriptions for controlled substances starting in January 2020:

> In an effort to continue to be part of the solution to our nation's opioid epidemic, Walmart is introducing new policies, programs and tools aimed at curbing opioid misuse and abuse. These initiatives apply to all Walmart and Sam's Club pharmacies and pharmacists in the United States and Puerto Rico.
>
> . . .
>
> Further, by the end of August 2018 . . . [i]n states that allow access, the company's pharmacists will have access to and use the controlled substance tracking tool, NarxCare. NarxCare is a tool that helps pharmacists make dispensing decisions and provides pharmacists with the real-time interstate visibility that currently exists.

461. What followed was a campaign by Walmart that focused less on bringing the company into compliance on its controlled substance programs and policies than on undermining the legitimacy of the grounds for the investigation and to exert political influence over prosecutorial decisions.[102] In March 2020, ProPublica published an article detailing Walmart's role in the opioid epidemic and detailing the company's efforts to undermine the efforts of investigators seeking to hold it accountable.

462. On September 14, 2020, Walmart issued a nine-page report summarizing the "important components of Walmart's response to the opioid crisis and the Board's oversight of Walmart's activities related to the dispensing of prescription opioid medications in the United States." The report asserted that "[a]s a whole and through its committees, Walmart's Board of

[102] *See, e.g.*, September 2017, 2019 Letter on behalf of Walmart from Karen Hewitt to Gustav W. Eyler, Director of DOJ's Consumer Protection Branch.

Directors oversees Walmart's risk management policies and practices, including related [sic] to prescription opioids." According to the report, the Board oversaw Walmart's "risk tolerance" and received "regular reports from Board committee chairpersons and members of senior management regarding risk-related matters." The report discussed the Audit Committee's oversight of global compliance and emphasized that the committee consisted "solely of independent directors."

463. As for steps that Walmart actually had taken to address the opioid crisis, the report highlighted the availability of NarxCare. The report then discussed Walmart's deference to its pharmacists' discretion in refusing to fill orders:

> We support our pharmacists when they exercise their professional judgment not to fill a controlled substance. Individual Walmart pharmacists may refuse to fill a particular prescription of concern (known as a "refusal to fill" or "RTF"), based on the presence of certain unresolved "red flags" (warning signs that a prescription might not be for a legitimate medical purpose) or combinations of unresolved red flags. If a pharmacist has more general concerns about a prescriber's controlled-substance prescribing practices, the pharmacist may refuse to fill all controlled-substance prescriptions written by that provider (a "blanket refusal to fill" or "BRTF").

464. This information contradicts numerous internal emails that demonstrate the routine guidance provided by Walmart's Health and Wellness department instructed Walmart pharmacists that they could not blanket refuse to fill prescriptions written by even the most problematic providers. Rather, Walmart pharmacists were instructed that they must evaluate each prescription separately.

465. On November 23, 2021, after six weeks of trial, a jury in the Opioid MDL found that two Ohio counties "prove[d] by the greater weight of the evidence" that Walmart "engaged in intentional and/or illegal conduct which was a substantial factor" in the "oversupply of legal prescription opioids, and diversion of those opioids into the illicit market outside of appropriate

medical channels."[103] The jury found that "widespread prevalence of opioid-use disorder . . . and addiction" was "the direct and foreseeable result of the 'oversupply of legal prescription opioids, and diversion of these opioids . . . ,' caused by [Walmart's] wrongful conduct."[104] The jury also found that Walmart engaged in "improper dispensing conduct" as "evidenced by [its] systemic failures to investigate and resolve red-flag prescriptions . . . ."[105] "[S]pecific evidence . . . demonstrated that [Walmart] dispensed massive quantities of red-flagged prescriptions without taking adequate measures to investigate or otherwise ensure the prescriptions were appropriately dispensed."[106] From this, "[t]he jury reasonably concluded that [Walmart] dispensed opioids without having in place effective controls and procedures to guard against diversion—controls and procedures they knew were required and knew they had not adequately employed."[107]

466. Susanne Hiland, a Walmart employee from the Health and Wellness Division, testified at trial that Walmart did not provide enough funding to pursue anti-diversion initiatives. Hiland testified that, as late as March 4, 2016, regional directors did not have access to refusal-to-fill reports. Hiland also confirmed that pharmacists could not determine from Walmart's system whether another Walmart pharmacy had refused to fill a prescription.

467. On November 15, 2022, Walmart announced that it had agreed to "a $3.1 billion nationwide opioid settlement framework designed to resolve substantially all opioid lawsuits and potential lawsuits by state, local, and tribal governments, if all conditions are satisfied."[108] The settlement did not resolve all of the opioid cases involving Walmart. Most notably, the DOJ's

[103] Abatement Order, *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804 (N.D. Ohio Aug. 17, 2022), 2022 WL 3443614 at *4, *appeal pending, Trumbull Cnty. v. Purdue Pharma, L.P.*, No. 22-3753 (6th Cir.).
[104] *Id*. at *13.
[105] *Id*. at *30.
[106] *Id*.
[107] *Id*. at *32.
[108] Press Release, Walmart, Inc., Walmart Announces Nationwide Opioid Settlement Framework (Nov. 15, 2022).

Delaware action remains pending. In the settlement, Walmart agreed to implement expansive procedures and controls, including procedures to avoid the diversion of controlled substances. It is reasonable to infer that before the settlement, although Walmart had taken some steps over the years to improve its oversight policies, its policies remained inadequate.

4. Other Retail Pharmacies

468. The other unnamed associates being retail pharmacies, namely Kroger and Albertsons,[109] likewise sold massive quantities of opioids by failing to maintain effective controls against misuse and diversion and taking affirmative steps to undermine its own opioid diversion controls and those of others, and otherwise acted in concert with Defendants toward the mutual aim of violating the CSA and increasing their mutual financial benefit from their violations, acts, and omissions pertaining to prescription opioids.

F. A number of Defendants and Unnamed associates have been investigated and fined repeatedly for failing to secure their supply chains, but refuse to change their ways.

451. Defendants have failed to properly dispense and distribute opioids as required by the CSA and have been investigated on multiple occasions by governmental agencies, and sanctioned or fined related to those activities, as have other unnamed associates for their failure to secure their opioid supply chains and prevent drug diversion has resulted in years of governmental investigations. Notwithstanding these settlements and the egregious wrongdoing they uncovered, the Defendants and unnamed associates continued to violate their duties.

1. ABDC

452. In 2007, the DEA issued an immediate suspension order against an ABDC distribution center in Orlando, Florida for failing to maintain effective controls against

[109] In controlling its own docket, the court has ordered that this bellwether case shall name only Walmart, Walgreens and CVS.

hydrocodone diversion. As part of the agreement to restore the Orlando facility's license to ship controlled substances, ABDC publicly stated that it would "implement an enhanced and more sophisticated order monitoring program" nationwide.[110]

453. In 2012, the DEA subpoenaed ABDC regarding the company's failure to protect against diversion of controlled substances into non-medically necessary channels.[111]

454. In 2022, the Department of Justice filed a civil complaint against ABDC for its continued violations of the CSA through at least 2021.

2. Anda

455. An Anda subsidiary voluntarily surrendered its DEA registration, which authorized it to distribute controlled substances, to avoid further enforcement actions.[112]

456. Anda was sued by and settled with the Attorneys General of West Virginia and New York regarding its opioid distribution practices.[113]

3. Cardinal

457. In 2007 and early 2008, the DEA issued Warrants for Inspections, Orders to Show Cause, and Immediate Suspension Orders against four Cardinal distribution facilities for failure to maintain effective controls against diversion of hydrocodone.

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[110] AmerisourceBergen, AmerisourceBergen Signs Agreement with DEA Leading to Reinstatement of Its Orlando Distribution License to Distribute Controlled Substances (June 22, 2007), https://www.sec.gov/Archives/edgar/data/1140859/000119312507141013/dex991.htm.

[111] Jeff Overley, *AmerisourceBergen Subpoenaed by DEA Over Drug Diversion,* Law360 (Aug. 9, 2012), https://www.law360.com/articles/368498/amerisourcebergen-subpoenaed-by-dea-over-drug-diversion.

[112] Ranking Member's Off., U.S. Senate Homeland Sec. & Gov'tal Affairs Comm., *Fueling an Epidemic: Report Three* (2018), https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-A%20Flood%20of%201.6%20Billion%20Doses%20of%20Opioids%20into%20Missouri%20and%20the%20Need%20for%20Stronger%20DEA%20Enforcement.pdf

[113] *State Reaches $4.2M Settlement with Five Drug Companies*, W. Va. Record (June 23, 2016), https://wvrecord.com/stories/510936977-state-reaches-4-2m-settlement-with-five-drug-companies. *New York Attorney General Announces Settlement with Three Distributors Amid Long Island Trial* (July 20, 2021), https://www.law.com/newyorklawjournal/2021/07/20/new-york-attorney-general-announces-settlement-with-three-opioid-distributors-amid-long-island-trial/?slreturn=20210706151323.

458. In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion (the "2008 Cardinal Settlement Agreement").[114] These allegations included failing to report to DEA thousands of suspicious orders of hydrocodone.[115] As part of this settlement, Cardinal agreed to "maintain a compliance program designed to detect and prevent diversion of controlled substances as required by the CSA and applicable DEA regulations."[116]

459. However, in 2012, the DEA issued an immediate suspicious order against a Cardinal facility in Florida for failure to maintain effective controls against diversion of oxycodone.[117]

460. To settle this action, Cardinal agreed that it had (i) failed to maintain effective controls against the diversion of controlled substances, including failing to conduct meaningful due diligence; (ii) failed to detect and report suspicious orders; and (iii) failed to adhere to the provisions of the 2008 Cardinal Settlement Agreement.[118] As part of the 2012 settlement, Cardinal agreed to cease distributing controlled substances from the Florida facility for two years.[119]

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[114] Cardinal Health Inc., Agrees to Pay $34 Million to Settle Claims that it Failed to Report Suspicious Sales of Widely-Abused Controlled Substances, U.S. Dep't Just. (Oct. 2, 2008), https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

[115] *Id.*

[116] *Id.*

[117] Order to Show Cause and Immediate Suspension of Registration, *Cardinal Health* (U.S. Drug Enf't Admin. Feb. 2, 2012); *DEA Suspends Pharmaceutical Wholesale Distributor and Retailers' Ability to Sell Controlled Substances*, U.S. Dep't Just. (Feb. 6, 2012), http://s3.amazonaws.com/fcmd/documents/documents/000/003/349/original/Cardinal_Health_-_DEA_Suspension_of_Lakeland_FL_12DEAPR.pdf?1429557281.

[118] Administrative Memorandum of Agreement (May 14, 2012), https://www.thehealthlawfirm.com/uploads/Cardinal%20Health%20-%20Memo%20of%20Agreement.pdf.

[119] *Cardinal Health Brings Resolution to Litigation with DEA Settlement*, Cardinal Health (May 15, 2012), https://s1.q4cdn.com/238390398/files/doc_news/2012/CAH_News_2012_5_15_General_Releases.pdf.

461. On December 23, 2016, Cardinal agreed to pay $34 million to resolve allegations that it violated federal law by failing to report suspicious orders of controlled substances.[120] In that settlement agreement, Cardinal acknowledged it had failed to:

a. "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. § 1301.74(b)";

b. "maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. § 1301.74, including the failure to make records and reports required by the CSA or the DEA's regulations for which a penalty may be imposed under 21 U.S.C. § 842(a)(5)"; and

c. "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305."

4. McKesson

462. In late 2005, the DEA began investigating McKesson for filling large quantities of hydrocodone and oxycodone orders for rogue internet pharmacies, then later notified McKesson that it had identified more than 2 million doses of hydrocodone delivered by McKesson to several rogue internet pharmacies during a three-week period.[121]

463. On May 2, 2008, McKesson agreed to pay more than $13 million in civil penalties for filling hundreds of suspicious opioid orders. McKesson also entered into an Administrative Memorandum of Agreement with the DEA, which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform the DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures

[120] Settlement Agreement (Dec. 20, 2106), https://media.bizj.us/view/img/10285208/cardinal-health-settlement.pdf; *United States Reaches $34 Million Settlement with Cardinal Health for Civil Penalties Under the Controlled Substances Act*, U.S. Drug Enf't Admin. (Dec. 27, 2016), https://www.dea.gov/press-releases/2016/12/27/united-states-reaches-34-million-settlement-cardinal-health-civil.
[121] Memorandum from Michael Mapes to Joseph Rannazzisi (Jan 23, 2006).

established by its Controlled Substance Monitoring Program." [122]

464. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the future," including specific measures delineated in a "Compliance Addendum" to the Settlement.[123]

465. Despite this promise, McKesson paid $150 million in 2017 to resolve another investigation into its violations of the CSA. This investigation concluded that McKesson's desire for increased sales and retaining its customers overrode its obligations to report suspicious orders and jeopardized the health and safety of people around the country.

466. McKesson admitted that it "did not identify or report to the DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in DEA Letters" and that it failed to properly monitor its sales of controlled substances and/or report suspicious orders to the DEA, in accordance with McKesson's obligations under the 2008 Agreements, the CSA, and 21 C.F.R. § 1301.74(b)."[124]

467. McKesson further admitted that it had "distributed controlled substances to pharmacies even though those [McKesson] Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes.[125]

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[122] Settlement and Administrative Memorandum of Agreement (May 2, 2008) (hereinafter, "McKesson 2008 Settlement").
[123] *Id.*
[124] Settlement Agreement and Release (Jan. 5, 2017), https://www.justice.gov/opa/press-release/file/928471/download.
[125] *Id.* at 3, 4.

5. H.D. Smith

468. In December 2010, the DEA issued an administrative inspection warrant against H.D. Smith.

469. In November 2014, H.D. Smith was found in violation of Title 21, Code of Federal Regulations. A controlled substance accountability audit at H.D. Smith revealed that H.D. Smith did not maintain complete and accurate records of controlled substances distributed by H.D. Smith.

6. Schein

470. In 1998, Schein received a Cease and Desist letter from the Ohio State Board of Pharmacy for the sale of dangerous drugs to persons/entities not licensed/authorized to possess them.

471. In 2012, Henry Schein agreed to pay a $50,000 fine to settle civil allegations by the DEA stemming from distributions to a researcher at the University of Pittsburg who had been criminally charged in connection with the diversion of controlled substances.

472. In November 2012, Henry Schein's Director of Regulatory Operations, Sergio Tejeda, informed the Program Director for the Prescription Monitoring Program of the Ohio State Board of Pharmacy that Henry Schein had been under reporting sales of controlled substances to the Ohio Board of Pharmacy as required for the previous two years.

473. In 2014, Schein was investigated by the State of Ohio Board of Pharmacy due to its sale/distribution of wholesale dangerous drugs to an entity that did not have a valid Ohio license. It reached a settlement with the Ohio Board of Pharmacy related to this investigation in 2015.

474. In 2015, Schein's Indiana distribution center violated the CSA by failing to report to ARCOS the correct date of receipt of CS for all transactions.

475. In 2017, the Florida Department of Business and Professional Regulation issued a letter/Notice of Violation alleging that Schein distributed Rx drugs to Florida Practitioners from

its corporate office without obtaining permit to operate as an out-of-state Rx drug wholesale distributor.

7. Walgreens

476. In May 2006, the DEA sent Walgreens a Letter of Admonition, concluding that Walgreens's "formulation . . . for reporting suspicious ordering of controlled substances was insufficient."[126]

477. On April 7, 2011, Walgreens entered into a Settlement Agreement with the DEA regarding allegations of non-compliance with the Controlled Substance Act wherein Walgreens had agreed to "maintain a compliance program to detect and prevent diversion of controlled substances."[127]

478. On September 13, 2012, the DEA issued an Immediate Suspension Order and Order to Show Cause for Walgreens's Jupiter DC. The DEA found that the distribution center failed to comply with DEA regulations that required it to report suspicious drug orders Walgreens received from its retail pharmacies, resulting in at least tens of thousands of violations, particularly concerning massive volumes of prescription opiates.[128]

479. According to the DEA, Walgreens's corporate headquarters pushed to increase oxycodone sales at Walgreens's Florida pharmacies and provided bonuses for pharmacy employees based on the number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales.[129]

[126] Letter from Robert L. Corso, Special Agent in Charge, Detroit Field Division, U.S. Drug Enf't Admin., to Todd Polarolo, Distrib. Ctr. Manager, Walgreen Company (May 17, 2006).
[127] Admin. Memo. of Agreement (Apr. 7, 2011).
[128] 2012 Walgreens ISO, *supra*.
[129] *Id.*

480. In February 2013, the DEA issued similar Subpoenas and Warrant of Inspection on the Perrysburg DC. Walgreens employees made plans in preparation for the Perrysburg DC being "shut down" by the DEA, like the Jupiter DC.[130]

481. On June 10, 2013, Walgreens entered into a Settlement and Memorandum of Agreement ("MOA") with the DEA to resolve outstanding allegations involving the Walgreens distribution centers and pending actions concerning six Walgreens retail pharmacies. Walgreens agreed to pay $80 million to resolve DEA's claims that Walgreens allowed controlled substances, including oxycodone, to be diverted into the black market. In addition, Walgreens agreed to surrender its Jupiter DC's registration to distribute or dispense controlled substances for two years. As part of the MOA, Walgreens admitted that Walgreens's "suspicious order reporting for distribution to certain pharmacies did not meet the standards identified by the DEA in three letters from the DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including Walgreens, on September 27, 2006, February 7, 2007, and December 27, 2007.[131]

8. CVS

482. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.[132]

483. In May 2015, CVS agreed to pay a $22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed

[130] Letter from Alice S. Fisher, Philip J. Perry, Latham & Watkins LLP, and David S. Weinstein, Clarke Silverglate, P.A., to C. Lee Reeves, II, Scott Lawson, Wayne Groves, Drug Enf't Admin. (Feb. 20, 2013).
[131] Settlement & Memo. of Agreement (June 10, 2013); *Walgreens Agrees to Pay*, *supra.*
[132] *CVS to Pay $11 Million To Settle Civil Penalty Claims Involving Violations of Controlled Substances Act*, U.S. Dep't Just. (Apr. 3, 2013), https://www.justice.gov/usao-wdok/pr/cvs-pay-11-million-settle-civil-penalty-claims-involving-violations-controlled.

prescription opioids "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."[133]

484. In August 2015, CVS entered into a $450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled forged prescriptions with invalid DEA numbers and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone even though these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had record-keeping deficiencies.[134]

485. In February 2016, CVS paid $8 million to settle allegations that, from 2008 to 2012, CVS stores in Maryland filled prescriptions with no legitimate medical purpose.[135]

486. In June 2016, CVS agreed to pay $3.5 million to resolve allegations that 50 of its stores in Massachusetts and New Hampshire violated the Controlled Substances Act by filling forged prescriptions for controlled substances – mostly addictive painkillers – more than 500 times between 2011 and 2014.[136]

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[133] *United States Reaches $22 Million Settlement Agreement with CVS For Unlawful Distribution of Controlled Substances*, U.S. Dep't Just. (May 13, 2015), https://www.justice.gov/usao-mdfl/pr/united-states-reaches-22-million-settlement-agreement-cvs-unlawful-distribution.

[134] *Drug Diversion Claims Against CVS Health Corp. Resolved With $450,000 Civil Settlement*, U.S. Dep't Just. (Aug. 10, 2015), https://www.justice.gov/usao-ri/pr/drug-diversion-claims-against-cvs-health-corp-resolved-450000-civil-settlement.

[135] *United States Reaches $8 Million Settlement Agreement with CVS for Unlawful Distribution of Controlled Substances*, U.S. Dep't Just. (Feb. 12, 2016), https://www.justice.gov/usao-md/pr/united-states-reaches-8-million-settlement-agreement-cvs-unlawful-distribution-controlled.

[136] *CVS to Pay $3.5 Million to Resolve Allegations that Pharmacists Filled Fake Prescriptions*, U.S. Dep't Just. (June 30, 2016), https://www.justice.gov/usao-ma/pr/cvs-pay-35-million-resolve-allegations-pharmacists-filled-fake-prescriptions.

487. In July 2017, CVS paid a fine of $5 million in a settlement with the DEA and the United States to resolve allegations that its pharmacies in the Eastern District of California failed to keep and maintain accurate records of controlled substances. CVS admitted that the numerous retail stores covered by this settlement violated their record-keeping obligations.[137]

488. In August 2018, CVS paid a civil penalty of $1 million to resolve record-keeping violations at CVS Pharmacy locations throughout the Northern District of Alabama.[138]

9. Walmart

489. Walmart received more than 50 Letters of Admonition from the DEA for its dispensing practices from 2000 to 2018.

490. In 2007 and 2008, Walmart paid two settlements to resolve actions arising from CSA violations—one for filling unlawful prescriptions and the other for record-keeping violations.

491. Federal prosecutors took action against five Walmart and Sam's Club Pharmacies in Texas, alleging that they failed to maintain records required by the CSA.[139] A U.S. Attorney further explained that "[b]ecause of the pharmacies' lack of proper record keeping, a variety of Schedule II, III, IV and V controlled substances were lost or stolen and possibly diverted."[140]

492. Following its settlement of this action in 2009, Walmart claimed that the agreement only pertained to a handful of stores in that state and claimed that Walmart was "eager to comply with the law." A Walmart spokesperson further claimed, "We take record keeping seriously[,]"

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[137] *CVS Pharmacy Inc. Pays $5M to Settle Alleged Violations of the Controlled Substance Act*, U.S. Dep't Just. (July 11, 2017), https://www.justice.gov/usao-edca/pr/cvs-pharmacy-inc-pays-5m-settle-alleged-violations-controlled-substance-act.

[138] *CVS Pharmacy Pays $1 Million Penalty in Settlement with DOJ for violations of the Controlled Substances Act*, U.S. Dep't Just. (Aug. 21, 2018), https://www.justice.gov/usao-ndal/pr/cvs-pharmacy-pays-1-million-penalty-settlement-doj-violations-controlled-substances-act.

[139] Associated Press, *Wal-Mart Settles Drug Records Accusation* (Jan. 7, 2009), https://chainstoreage.com/news/wal-mart-settles-drug-records-accusations (hereinafter *Walmart Settles*)

[140] Richard Connelly, *Now We Know Why Wal-Mart Has That Smiley Face*, Hous. Press (Jan. 7, 2009), https://www.houstonpress.com/houston/Print?oid=6724828.

and "[w]e continuously review our processes at our pharmacies to ensure they are accurate and in full compliance with the law." [141]

493. In 2009, the DEA issued a Show Cause order seeking to revoke the registration of a Walmart pharmacy in California. The order alleged that the pharmacy:

> (1) improperly dispensed controlled substances to individuals based on purported prescriptions issued by physicians who were not licensed to practice medicine in California; (2) dispensed controlled substances . . . based on Internet prescriptions issued by physicians for other than a legitimate medical purpose and/or outside the usual course of professional practice . . . ; and (3) dispensed controlled substances to individuals that [the pharmacy] knew or should have known were diverting the controlled substances.

494. To resolve the 2009 proceeding, Walmart entered into an MOA with the DEA in 2011. It stayed in effect through March 2015. Upon information and belief, the failures described in the 2011 MOA were not limited to California but reflected systemic failures at the corporate level. Indeed, the 2011 MOA required Walmart to adopt a national compliance program that applied to "all current and future Walmart Pharmacy locations." It also required Walmart to collect reports from its pharmacists when those pharmacists determined that controlled-substance prescriptions were invalid and refused to fill them.

495. The 2011 MOA specifically required that Walmart implement procedures to make certain that pharmacists identified red flags:

> The program shall include procedures to identify the common signs associated with the diversion of controlled substances including but not limited to, doctor-shopping, requests for early refills, altered or forged prescriptions, prescriptions written by doctors not licensed to practice medicine in the jurisdiction where the patient is located, and prescriptions written for other than a legitimate medical purpose by an individual acting outside the usual course of his professional practice.

[141] Associated Press, *Wal-Mart Settles Drug Records Accusation* (Jan. 7, 2009), http://prev.dailyherald.com/story/?id=262762.

496. During the four-year term of the 2011 MOA, Walmart required pharmacists to document a refusal to fill on a refusal-to-fill form. Walmart received these forms and so learned about problematic prescribing practices. Yet, Walmart did not utilize this information to alert its pharmacists about possible, or known, pill-mill prescribers. Walmart did not even educate nearby stores to which a customer was likely to take a refused prescription. It was particularly important for Walmart to do this because its pharmacists did not always work overlapping shifts and some of its pharmacists "floated" between several stores, thereby reducing the pharmacists' ability to communicate their concerns directly to one another.

497. In October 2018, the DOJ had evidence that Walmart pharmacies in Texas dispensed opioids that killed customers who overdosed on the drugs. "The pharmacists who dispensed those opioids had told the company they didn't want to fill the prescriptions because they were coming from doctors who were running pill mills," but their pleas "for help and guidance from Walmart's corporate office" fell on deaf ears.[142]

498. A Texas federal prosecutor, in connection with an investigation that began in 2016, concluded, "Walmart had a national problem."[143]

499. The investigation reportedly revealed that between 2011 and 2017, "Walmart pharmacists repeatedly filled prescriptions that they worried were not for legitimate medical purposes, including large doses of opioids and mixtures of drugs DEA considered red flags for abuse." They did so even though Walmart pharmacists "raised alarms to the company's national compliance department about doctors."[144]

[142] Eisinger & Bandler, *supra.*
[143] *Id.*
[144] *Id.*

500. More recently, Walmart reportedly claimed to be cooperating with a federal investigation and "taking action to fix its opioid dispensing practices." In fact, however, Walmart subsequently "acknowledged that it halted its cooperation in mid-2018."[145]

501. In December 2020, the U.S. Department of Justice (the "DOJ") filed a civil complaint against Walmart in the U.S. District Court for the District of Delaware.[146] The DOJ sought injunctive relief to restrain Walmart's continuing violations of the law and alleged that Walmart repeatedly violated the Controlled Substances Act, both as a dispenser and as a distributor.[147] The DOJ alleged that from June 2013 to November 2017, Walmart reported only 2,014 suspicious orders to the DEA, even though it shipped an estimated 37.5 million orders of controlled substances to its pharmacies. By comparison, Walmart's backup distributor, McKesson Corporation, reported more than 13,000 suspicious orders from Walmart's pharmacies during the same period, despite fulfilling far fewer orders.[148]

G. Defendants misrepresented that they were complying with their duties to prevent diversion of opioids and to ensure that the conducted their corresponding responsibility to ensure dispensed opioids were for a legitimate medical purpose.

502. Defendants and the unnamed associates misrepresented to the public that they were complying with their statutory duty to identify, halt, and report suspicious orders of opioids, and properly conduct their corresponding responsibility in dispensing opioids under the CSA. In so doing, they deceptively concealed their role in creating and perpetuating the opioids crisis. Defendants' repeated payments of fines and other enforcements actions indicates that these statements were false.

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[145] *Id.*
[146] *See* Complaint, *United States v. Walmart Inc.*, No. 1:20-CV-01744-CFC (D. Del. Dec. 22, 2020).
[147] Compl. ¶¶ 300, 350; Dkt. 40 at 24.
[148] Compl. ¶ 25.

503. For example, in connection with a DEA settlement, Walgreens publicly stated that it would maintain a compliance program to detect and monitor diversion, including training its pharmacists on red flags for diversion, but it has failed to implement a program to adequately do so.[149] Walgreens continues to maintain that it "has taken a number of actions over many years to respond to the opioid crisis . . . including . . . [d]eploying technology to help pharmacists ensure they are dispensing prescriptions written for a legitimate medical purpose,"[150] while ignoring the existence of corporate policies that actively encouraged dispensing controlled substances.

504. Similarly, CVS CEO Larry Merlo described his company as "America's front door to health care with a presence in nearly 10,000 communities across the country," which allowed it to "see firsthand the impact of the alarming and rapidly growing epidemic of opioid addiction and misuse."[151] According to its website:

> CVS Health® has made a commitment to help address the misuse of prescription opioids by designing programs and collaborating with community leaders, policymakers, law enforcement, health care professionals and others to increase community-based educational programs related to opioid misuse, create safe prescription drug disposal sites, expand access to life-saving antidotes and advocate for targeted and effective policies, locally and nationally.[152]

CVS's statement fails to mention CVS's own role in promoting and enabling the widespread use of prescription opioids.

505. Through nationwide advertising, Walmart presented a public image of the safety and excellence of all the pharmacists the company hired. For example, in a recruitment video for

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[149] Settlement & Memo. of Agreement (June 10, 2013).
[150] *Walgreens Announces Agreement in Principle for Multi-State Opioid Settlement Framework*, Walgreens (Nov. 2, 2022), https://news.walgreens.com/press-center/news/walgreens-announces-agreement-in-principle-for-multi-state-opioid-settlement-framework.htm.
[151] *See, e.g.*, David Salazar, *CVS Health Unveils New PBM, Pharmacy Efforts to Curb Opioid Abuse*, (Sept. 21, 2017), https://drugstorenews.com/pharmacy/cvs-health-unveils-new-pbm-pharmacy-efforts-curb-opioid-abuse.
[152] *Our Opioid Response*, CVS, https://www.cvshealth.com/impact/healthy-community/our-opioid-response.html (last visited Aug. 23, 2022).

pharmacists on Walmart's YouTube channel, the company shows Walmart pharmacists speaking about working at the company: "the safety and the excellence we carry to our patients is phenomenal," adding that "the culture that our company has [is] respect for the individual, service, and excellence, and, of course, we always have integrity." The commercial also states that Walmart's pharmacists "strive for excellence" and are "passionate about providing quality healthcare."[153]

506. Walmart's website states, "Our pharmacists are trained to check for indicators of potential concern before filling each prescription,"[154] a statement that ignores Walmart's repeated efforts to impede its own pharmacists' ability to do so.

507. Defendants made some of these statements and material omissions through their trade organizations, including the Healthcare Distribution Alliance as well as the National Association of Chain Drugstores, of which Walgreens, Walmart, and CVS are or have been members.[155] Each of the Distributor Defendants are members of the HDA and its predecessor entities. Defendants committed other activities through the NACDS and HDA to thwart enforcement actions, to improperly avoid liability for their CSA obligations, and to misrepresent their compliance with their CSA obligations, among other failures. Through membership and leadership positions in the NACDS, Defendants coordinated to grow and protect the opioid supply chain. Toward their scheme to avoid and violate their CSA obligations, Defendants—for their mutual financial benefit, and to improperly maintain the inflated supply chain—coordinated their

[153] Walmart, *Your Career as a Walmart Pharmacist*, YouTube (Sept. 25, 2014), https://www.youtube.com/watch?v=9VD12JXOzfs.
[154] *Stewardship*, Walmart, https://corporate.walmart.com/stewardship (last visited Aug. 18, 2023).
[155] *NACDS Member Retailers (US-based)*, Nat'l Ass'n Chain Drug Stores, https://www.nacds.org/membership/directories/chain-companies/ (last visited Aug. 25, 2023); Sandra Levy, *CVS Health Breaks with NACDS, Remains Committed to Advancing, Supporting Value of Pharmacy*, Drug Store News (July 4, 2022), https://drugstorenews.com/cvs-health-breaks-nacds-remains-committed-advancing-supporting-value-pharmacy.

activities, formed mutual policies on controlled substances and, hence, in common manners violated their CSA obligations. Likewise, the worded in partnership with each other and the HDA, and Pain Care Forum, to develop mutual strategies of marketing and activities to avoid and deter DEA enforcement, avoid and breach their CSA obligations, with and through these mutual strategies and policies. These activities and mutual, coordinated actions were not innocuous, but further to their common goal of violating the CSA for their mutual financial benefit and to obtain an unlawful objective. Defendants committed these actions through actual or tacit agreements with each other and unnamed associate co-conspirators.

508. Defendants' misrepresentations misled the public and ultimately delayed an adequate response to the opioid crisis. Further to their conspiracy, Defendants each committed the violations and unlawful activities complaint of infra, including violations of the CSA, jointly toward this conspiracy and also separately, and in common manners, and with a common conspiratorial objective.

H. The Defendants marketed the Manufacturing Associates' opioids.

1. Walgreens

509. Walgreens worked with the unnamed associates to promote the falsehoods stated above. Purdue leveraged its relationship with Walgreens and their mutually beneficial goal of growing the opioid business to ensure that Purdue had input into the "corporate guidelines" that Walgreens's pharmacists were "expected to follow" when it came to dispensing prescription opioids.

510. Starting in at least 1999, Purdue sponsored Walgreens's continuing education programs designed to encourage stores to "get on the Pro Pain Management Band Wagon."

511. Walgreens's Market Director of Pharmacy Operations recommended that Walgreens's District Managers and Pharmacy Supervisors attend a continuing education program

titled *The Pharmacists' Role in Pain Management: A Legal Perspective*, which was available online at RxSchool.com.[156] The program was eventually made mandatory.

512. Through this and other programs, Purdue and Walgreens disseminated fraudulent information that redefined red flags in an effort to correct pharmacists' supposed "misunderstanding" about pain patients and the practice of pain management.

513. Walgreens's Market Director of Pharmacy Operations also recommended an Endo-sponsored continuing education program, *Navigating the Management of Chronic Pain: A Pharmacist's Guide*, which disseminated manufacturer messaging and misinformation designed to broaden the market for opioids.

514. Walgreens worked with the unnamed associates to promote the falsehoods stated above.

2. CVS

515. To grow the demand for prescription opioids, CVS participated in the marketing, advertising, and promotion of opioid products with and on behalf of opioid manufacturers.

516. For example, CVS made at least one pitch to Insys, a company whose senior executives were criminally convicted for their unlawful marketing, to help promote a liquid form of fentanyl. CVS touted the reach of its communications and explained the science behind its marketing, advertising, and promotional services. Through CVS's NEWScript program, CVS claimed to be perfectly poised to assist with new-product launches. CVS even offered Insys the chance at having a literature display in its patient waiting rooms and to help Insys "target patients" using its signature ExtraCare consumer loyalty card database.

[156] *See* Walgreen Co. Controlled Substance Anti-Diversion and Compliance Program (July 17, 2012).

517. CVS also worked with Purdue to ensure that CVS pharmacists were trained by Purdue on many of Purdue's misleading marketing messages. Purdue's and CVS's tactics included distributing internal Purdue memos and misinformation concerning opioids, on which CVS even used Purdue's logos.

518. The Purdue memo describing these tactics reveals that they were supported by CVS's leadership, including its directors of quality improvement and regulatory compliance and its Manager of Professional Practices.

519. CVS worked with Endo to increase patient adherence to continued use of opioids. CVS had a crucial role in carrying out one of the key sales tactics in Endo's 2012 business plan.

520. Through a company called Catalina Health ("Catalina"), Endo was able to target OxyContin patients in areas where Opana ER had preferred formulary status. Catalina in turn worked to create a brand-loyalty program that kept new patients on their opioids. CVS, through its pharmacy-retention programs, sent letters to the patients' homes to encourage them to stay on Opana.

521. The agreement between CVS and Endo was formalized in an agreement to promote, market, and advertise Endo's opioid products via its "CVS Carecheck Plus Patient Education Service." CVS not only contractually agreed to promote Opana ER to its customers (i.e., patients) at the point of sale, it even insisted upon reviewing and approving the specific messaging used.

522. CVS helped Actavis promote its opioids by working with Cardinal's Marketing and Business Development team on programs designed to offer rebates and off-invoice discounts on products, with the aim being to "move [] product."

3. Walmart

523. Walmart worked with the unnamed associates to promote the falsehoods stated above. Walmart teamed up with Purdue to spread misinformation about prescription opioids. As

early as 1995, Purdue and Walmart launched presentations utilizing pro-opioid KOLs to pharmacists across the country.

524. Between August 1, 2009, and May 31, 2010, Walmart participated in a program in connection with Actavis' Kadian aimed at "improv[ing] patient persistence and increas[ing] the overall length of therapy by providing patients with education on [Kadian], tips to help manage pain, and timely, behavior-triggered refill reminders."

525. Walmart circulated a Purdue-sponsored continuing education program titled "Should I Dispense This? Recognizing Appropriate Pain Management" and a pamphlet titled "Counseling Patients & Their Families on the Role of Opioid Analgesics in Pain Management: A Pharmacist's Guide" to its pharmacists. Together, these materials discussed pseudoaddiction, downplayed the addiction risks associated with Purdue's opioid products, and encouraged proactive opioid prescriptions to prevent pain before it even begins.

526. Walmart participated in a twelve-month collaborative program between Purdue and Adheris beginning October 16, 2013, "designed to improve patient adherence on Butrans."

527. Walmart distributed promotional materials authored by the American Pharmacists Association, a member of the Pain Care Forum

I. Defendants coordinated their schemes through trade associations.

528. Defendants worked together to achieve their common purpose, conspiracy, unlawful activities, and coordination of unlawful acts, as detailed herein, through trade or other organizations, such as the Pain Care Forum ("PCF"), the Healthcare Distribution Alliance ("HDA") (formerly known as the Healthcare Distribution Management Association ("HDMA")), and the National Association of Chain Drug Stores ("NACDS").

529. These organizations provided repeated opportunities for members of the Opioid Promotion Enterprise to coordinate their activities and to arrange for the endorsement of their scheme by ostensibly independent or third-party organizations.

1. Pain Care Forum

530. The Pain Care Forum was a coalition of drugmakers, trade groups, and dozens of non-profit organizations supported by industry funding, including the Front Groups described in this Complaint. Lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade. PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[157]

531. The PCF was organized in 2005 by Purdue's Burt Rosen and others. Purdue, Cephalon, J&J, and APF were among its early participants. Members eventually included Abbott, Endo, Teva, Grünenthal, the HDMA, NACDS, FSMB, PhRMA, and APPM.

532. The PCF allowed the Manufacturing Associates and the Distributor Defendants to engage in coordinated conduct to ensure an oversupply of opioids. The PCF's entire purpose was coordinating industry activities surrounding pain and opioids. For instance, Rosen explained in 2005, "I think this could fill the vacuum of leadership in the community at large and provide for some unified direction on issues of importance to the pain community." In the initial email to the founding members, Rosen explained that the goal was "to coordinate and focus commitments to actions regarding public policy issues that affect the treatment of pain."

[157] Matthew Perrone, *Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic*, Ctr. for Pub. Integrity (Sept. 19, 2017), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic.

533. Members met monthly in Washington, D.C. but could also participate by phone. The meetings deliberately excluded the media, and no minutes were taken in order to keep the meetings off the record.

534. In 2007, APF and Purdue collaborated on talking points for use at a Pain Care Forum meeting. Some of these talking points included "[o]verly restrictive regulatory policies impeded pain relief"; "doctors and people with pain" who "believe that opioid medications are addictive" constituted "barriers to effective pain care"; and opioid medications "give relief—not a 'high.'"[158]

535. Members of the PCF worked together in an attempt to delay or halt the rescheduling of hydrocodone combination products such as Norco and Vicodin from Schedule III to Schedule II because the rescheduling, by imposing stricter requirements for prescribing and dispensing, would reduce sales. This effort was ultimately unsuccessful as hydrocodone was rescheduled in 2014.

536. The Manufacturer Defendants used the PCF to "coordinate strategy and to address the FDAs REMS proposals." In 2007, Congress gave the FDA authority to require Risk Evaluation and Mitigation Strategies ("REMS") that would increase various safety measures for high-risk drugs, including requiring specialized training for prescribers. Around 2008, the FDA was contemplating a REMS program for long-acting and extended-release (LA/ER) opioids and asked the Manufacturer Defendants to form an Industry Working Group to coordinate their position. The FDA Industry Working Group meetings, however, were on the record and, because the Manufacturing Associates are direct competitors, were attended by antitrust counsel. The FDA did

[158] Treatment Options, *supra* at 5.

not invite the distributors or Front Groups to participate. The PCF, therefore, created its own REMS Task Force that included these groups.

537. The PCF's REMS Task Force reviewed a draft letter to the FDA recommending mandatory physician and pharmacist training and certification requirements as a prerequisite to prescribing and dispensing LA/ER opioids. The PCF, working with the HDA, deleted that part, stating "we shouldn't mention a 'certification' requirement for physicians (or anyone else for that matter.)" The final letter to the FDA did not mention the HDA's or the PCF's role in drafting the letter. The PCF also prepared form "recommendations" for its Front Group members to use to submit comments to the FDA on REMS. When one PCF member raised concern that the FDA "may feel it was rather duplicitous of the [industry members] to meet with [the FDA commissioner] and not mention that these were in the works," he was told, "It's the way things work" and there was a "need to keep silent on the congressional and media strategies."

538. The Manufacturer Defendants collaborated through the PCF to coordinate opposition to the CDC's opioid prescribing guidelines before they were even issued. The CDC guidelines were "not good news" for the opioid industry and the PCF had formed a "broad work group" that included plans to "criticize the CDC process and expected outcomes" using "media efforts and recruiting patients and provider experts." Indeed, by this time the Manufacturer Defendants knew that state-implemented prescribing guidelines hurt their opioid sales. And since at least 2012 they and other PCF members, including the HDA, had worked together to convince the CDC that the true epidemic was untreated chronic pain, that it was the "#1 public health problem in the United States," was the true epidemic, and that it was "unclear" why what PCF members euphemistically referred to as "opioid-related problems" were "considered to be of epidemic proportions." Once the CDC released its guidelines, the Manufacturer Defendants used

the PCF to undermine the guidelines because they were concerned that the guidelines were "likely to dampen opioid sales in the US" and "impact[] prescription habits globally."

539. The Manufacturing Associates also used the PCF as a forum to actively coordinate their activities. For instance, Grünenthal USA's Dan Cohen led PCF's Abuse Deterrent Formulations Coalition, which presented to the PCF's Communications Working Group on conference calls and coordinated activities to promote use of prescription opioid ADFs (despite the fact that ADFs do nothing to ameliorate the risk of the most common route of misuse—oral ingestion of pills) along with other Defendants, including Janssen, Purdue, Endo, and Mallinckrodt.

540. PCF and the HDA worked together on many issues, including the HDA's Industry Compliance Guidelines, hydrocodone rescheduling, the creation of REMS for prescription opioids, issues related to diversion and SOM, and passage of the Marino bill.[159]

541. The HDMA and its members actively worked with other PCF members on various issues, including the HDA's Industry Compliance Guidelines, hydrocodone rescheduling, the creation of REMS for prescription opioids, and policies related to diversion and SOM. For instance, in 2008, an ABDC employee emailed Purdue explicitly asking for a meeting between the Purdue employee organizing the PCF and two ADBC's vice presidents to "talk about our issues and how to work with the coalition"—the PCF. Similarly, in March 2008, HDA's Senior Vice President for Government Affairs emailed Burt Rosen and Lisa Robin with FSMB to discuss the interest of some of HDA's members such as Cardinal and McKesson with supporting publishing or distributing Fishman's *Responsible Opioid Prescribing*.

[159] This bill was later reintroduced as the Hatch-Whitehouse bill and ultimately enacted as the Ensuring Patient Access and Effective Drug Enforcement Act.

542. Defendants' collaboration was particularly evident in activities by HDMA and NACDS to pass a 2014 bill (the "Marino bill") in Congress weakening DEA's authority to enforce the CSA against distributors. HDMA and NACDS coordinated this activity with other members of the PCF. Purdue and its outside lobbyist were the source for the critical language in the bill that accomplished the intended weakening. Non-industry PCF members signed letters in support of the bill. After the bill was passed, a Purdue representative emailed a Cardinal employee to congratulate him on their collective efforts in support of the bill.

543. Participants in PCF actively communicated with employees of Indivior (then Rickett Benckiser) as evidenced by 2012 emails. These emails concerned interactions with individuals involved in the Researched Abuse Diversion and Addiction Surveillance program ("RADARS"). Purdue had created RADARS in 2001 to satisfy the FDA and the DEA that it was tracking misuse of its products, primarily OxyContin, and cases where healthcare providers were diverting the pills to their own use or to sell for illicit purposes. Purdue sold the RADARS system to Denver Health in 2005, but even after the move to Denver Health, RADARS staffers have continued to argue against stricter limitations on prescription opioids before multiple legislatures, the FDA, and the DEA. They have also supported Purdue, other Manufacturing Associates, and the Front Groups to continue the Opioid Promotion Enterprise, including in authoring and co-authoring articles with Purdue, other opioid manufacturers, and the KOLs.

2. Healthcare Distribution Alliance

544. Cardinal, ABDC, McKesson, H.D. Smith, and Schein and Defendants belong to a trade association known until 2016 as the Healthcare Distribution Management Association and now known as the Healthcare Distribution Alliance.[160] The HDA was also a member of the PCF.

[160] *Our People*, Healthcare Distrib. All., https://www.hda.org/our-people/ (last visited Aug. 25, 2023).

545. The HDA and its members eagerly sought the active membership and participation of the Manufacturing Associates by advocating the many benefits for members, including "strengthen[ing] your alliances."[161] AbbVie, Endo, Hikma, J&J, Mallinckrodt, Par, Purdue, and Teva are or have been members of the HDA.[162]

546. The closed meetings of the HDA's councils, committees, task forces, and working groups provided the Manufacturing Associates and the Distributor Defendants and Defendants the opportunity to work closely together, confidentially, to develop and further their common purpose.

547. One time this happened was following suspensions of ABDC's, McKesson's, and Cardinal's distribution licenses for certain facilities in 2007 and 2008. These suspensions, which were a direct threat to the entire opioid industry's continued business, lit a fuse within the industry. The very real threat of DEA enforcement prompted a flurry of communication and coordination among all members of the supply chain, including members of the PCF, HDA, and NACDS, to find a solution to protect their businesses. As early as November 2007, HDA and NACDS jointly discussed a response to the DEA's initiative. One of HDA's goals, which it shared with , was to "develop a comprehensive DEA strategy" to avoid enforcement actions against distributors. As part of this strategy, Defendants, including through the HDA and NACDS, discussed the CSA's legal requirements, including the fact that distributors were required not to ship suspicious orders, and what their response should be.

548. The HDA voted as to whether, if "an order is potentially suspicious, should the distributor be able to ship part of the order "consistent with the current practice for many

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[161] *Manufacturer Membership Benefits*, Healthcare Distrib. All., https://web.archive.org/web/20220326010637/https://www.hda.org/~/media/pdfs/membership/manufacturer-membership-benefits.ashx (last accessed Aug. 25, 2023 as of Mar. 26, 2022).

[162] *Manufacturer*, Healthcare Distrib. All., https://web.archive.org/web/20221003150121/https://www.hda.org/about/membership/manufacturer (last access Aug. 25, 2023 as of Oct. 3, 2022).

distributors." HDA members also asked, "Should we support DEA's [law enforcement] efforts?" In advance of this vote, HDA requested that each of the unnamed Distributors and Defendants provide a representative "authorized to speak on, and agree to, policy and strategy decisions on behalf of their companies."

549. The unnamed Distributors and Defendants met face-to-face at the HDA on March 1, 2011, to discuss DEA regulations and order monitoring.

550. In 2012, the DEA issued an interim suspension of the license of a Cardinal distribution facility. At issue was an 803% increase in opioid sales to a pharmacy that Cardinal had already been fined for selling opioids to. In response, Cardinal filed a motion for a temporary restraining order. Shortly thereafter, on April 6, 2012, Cardinal, ABDC, and McKesson met under the auspices of the HDA to "plot a course forward."[163] Their plan, which they concocted jointly, was to involve a media campaign, focus groups to explore messaging that would paint the distributors in a positive light, a crisis playbook that included a written plan for responding to various scenarios (including registration suspension and a diversion lawsuit),[164] and a plan to arrange a congressional inquiry designed to paint the DEA as "misdirected." Defendants used the crisis playbook to develop talking points based on it; these were thus points that had previously been approved of by all of the Defendants participating in the HDA.

551. Another example occurred in 2013 at an HDMA meeting where Cardinal representatives told representatives from other distributors (including ABDC and McKesson) that Cardinal did not report suspicious orders to DEA because there was no advantage to Cardinal in making the required reports.

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[163] *See also* Healthcare Mgm't & Distrib. All., HDMA Political Strategy for DEA Suspicious Orders Matter (n.d.).

[164] Healthcare Mgm't & Distrib. All., *Crisis Playbook: An Interactive Guide to Crisis Communications* (n.d.), https://wp-stat.s3.amazonaws.com/graphics/opioid-files/pdfs/440.pdf (last visited Aug. 25, 2023).

552. HDA's Jewelyn Cosgrove emailed all of the members of the PCF to ask them, particularly the Front Group members, to sign onto a "group support letter" to be released with the re-introduction of the Marino Bill. She later acknowledged that it "couldn't have" been passed with the PCF's "help."

553. Defendants also participated, through the HDA, in webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices. For example, on April 27, 2011, the HDA offered a webinar to "accurately and effectively exchange business transactions between distributors and manufacturers. . . ." On information and belief, the Manufacturing Associates used this information to gather high-level data regarding overall distribution and to direct the Distributor Defendants on how to most effectively sell prescription opioids.

554. Publications and guidelines issued by the HDA confirm that Defendants utilized their HDA membership to form agreements. Specifically, in the fall of 2008, the HDA published *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances* (the "Industry Compliance Guidelines") regarding diversion.[165] As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of "[a] committee of [HDA] members contribut[ing] to the development of this publication" beginning in late 2007.[166] HDA falsely represented to that court that Cardinal did not have any input on the amicus brief and did not participate in the drafting of that brief.

[165] Healthcare Distrib. Mgm't All., Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (n.d.).

[166] *Amicus Curiae* Brief of Healthcare Distribution Management Association in Support of Cardinal Health's Motion for Injunction Pending Appeal 5, *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. filed Mar. 7, 2012).

555. As part of its "roll out" of the Industry Compliance Guidelines, HDA scheduled meetings with NACDS and with the manufacturer trade group PhRMA and specifically recognized NACDS and the PCF as "external stakeholders" in the guidelines.

556. Nevertheless, HDA knew that some of its largest members, including ABDC and Cardinal, would not implement these guidelines. The HDA even admitted internally that their purpose as to "[h]ead-off further enforcement or regulatory action" not to actually require compliance by the Distributor Defendants with their CSA obligations.

557. In an amicus brief filed by the HDA and the NACDS, Defendants and the unnamed associates represented that they were complying with their duties to identify suspicious orders by utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information available to them in the ordering process; taking action when particular orders or series of orders raised red flags because of size, frequency, or departure from patterns; and monitoring for unusual behavior by pharmacies. In this brief, they asserted:

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

b. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process." [167]

These statements were designed to give the false impression that Defendants were not deliberately turning a blind eye to egregious signs of diversion among their pharmacy customers.

558. Another example of the unnamed Distributors' control over the HDA occurred in 2017. Burt Rosen from Purdue emailed employees from ABDC, Cardinal, and McKesson to invite

[167] Brief for Healthcare Distribution Mgmt. Association and National Ass'n of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.*, No. 15-1335, 2016 WL 1321983, at *3–4, *25 (D.C. Cir. Apr. 4, 2016).

them to a meeting at Purdue's office for "brainstorming to determine if there is anything the Washington Offices may be able to do from a public policy perspective to better educate, or impact Washington policy makers thinking with respect to the litigation brought . . . against the opioid supply chain." The Distributor entities and Defendants clearly used HDA to distance themselves from direct communication with Purdue while nevertheless directing and benefiting from the results of the communication.

559. The unnamed Distributors and Defendants also collaborated with one another and with the unnamed Manufacturing Associates outside the HDA. For example, in November 11, 2010, H.D. Smith approached Cardinal Health about a "working group meeting to include representatives from the major wholesalers and possibly manufacturers," to discuss "how the major wholesalers could possibly collectively address due diligence efforts." The activities of the unnamed associates and Defendants through the HDA was toward, a part of, concerted acts, and in furtherance of their conspiracies to violate the CSA and other laws toward their mutual financial interests.

3. National Association of Chain Drug Stores

560. The National Association of Chain Drug Stores is a trade association that represents traditional drug stores, supermarkets, and mass merchants with pharmacies. Its members and affiliate members also include stakeholders such as manufacturers, other distributors, and other trade organizations.

561. Walgreens, Walmart, Rite Aid, Giant Eagle, Publix, Kroger, Albertsons, and CVS are or have been members of NACDS. In addition, ABDC, McKesson, Cardinal, Anda, and H.D. Smith are or have been associate supplier members. HDA and NACDS viewed the strategic "alliance" and overlapping membership between their organizations as important.

562. As controlling members of NACDS, Defendants and their agents have served on and run key governing committees within the organization. Many of them have served on and even chaired NACDS's Board of Directors, which determines the "strategic plan and positions" of NACDS. For example, in 2018, Walgreens, Rite, Aid, and Walmart representatives were elected to the board for 3-year terms. Current board members include representatives of Walmart (vice-chair), Walgreens (treasurer), Albertsons, Meijer, Kroger, Publix, and Rite Aid. In addition, Cardinal and McKesson were elected to the NACDS Board in 2009 and again in 2019.

563. Distributor Defendants were also able to serve on key committees alongside the Defendants, providing a forum for collaboration and a venue where the activities of the Opioid Promotion Enterprise could be coordinated. For example, McKesson served on the NACDS Strategic Communications Committee with Walmart, Walgreens, Rite Aid, and CVS and McKesson, and Cardinal received communications from the NACDS policy council along with the National Retail Pharmacies.

564. In 2008, Cardinal Health prepared talking points for a NACDS conference about its planned retail chain SOM program, making it clear that the program would "minimize the disruption" to retail chains and that they would "work together" with the pharmacies "to ensure that our Suspicious Order Monitoring program for retail chains does not interrupt" business." Cardinal stated that its "objectives" included "working in partnership" with the chain customers to effect "resolution" of a "suspicious order pattern…prior to supply chain disruption," by taking steps established by the Cardinal Health "Sales" department, such as allowing the customer/customer store" to set the thresholds and providing "early warning" communications "prior to a SOM event – for example, at 75% of threshold" for "sales to work with the account."

565. NACDS delayed effective progress towards establishing effective industry standards regarding red flags for dispensing prescription opioids. Defendants, working through NACDS, met to discuss developing such standards but ultimately decided not to adopt standards out of a fear that if they did not comply with their own standards, they would be subject to enforcement actions or litigation; Defendants, through the NACDS, coordinated and conspired to avoid and violate their CSA obligations, toward their mutual financial benefit.

566. NACDS members coordinated regarding pharmacy diversion "DEA red flags" through a "DEA Compliance Workgroup," seeking to focus on keeping the drugs flowing while promoting optics, noting that "policies that are too prescriptive … should not be included in the code" and citing meeting "pain control needs of patients" as a "Guiding Principle." Defendants further used an NACDS "Pharmacy Compliance Roundtable" to discuss avoiding criminal and civil liability for issues related to controlled substances, SOM, and diversion.

567. In 2014, when the HDA discussed a plan involving NACDS and PhRMA to develop a "Red Flags" guidance document for prescription opioids (much like the ICGs), HDA noted that the "subtext strategy . . . [was to] keep the DEA at bay."

568. NACDS also directly participated in the PCF. Chrissy Kopple of NACDS presented to the PCF's Communications Working Group regarding an early iteration of the Marino bill.

569. When the DEA attempted to reschedule hydrocodone combination products, which were common targets of misuse and diversion, Defendants banded together to attempt (ultimately unsuccessfully) to prevent their up-scheduling. NACDS reached out to the PCF to create a Task Force and included HDA representatives as well as numerous manufacturers. NACDS collaborated with the PCF "communications working group" and sent statements to media outlets claiming the rescheduling would "negatively impact access to needed medications for those who

suffer from chronic pain." The NACDS committee included CVS, Walgreens, McKesson, Rite Aid, and Giant Eagle. NACDS encouraged members to oppose HCP rescheduling, despite admitting the prescription drug abuse is "so bad" in certain states that legislators feel they must "do something." Defendants knew rescheduling from Schedule III to Schedule II would "tighten controls" on prescribers and reduce their sales.

570. In 2016, the NACDS Policy Council discussed ongoing efforts to shape opioid legislation, including their success in removing a requirement that pharmacists have to check their state drug monitoring program before filling controlled substance prescriptions. Members of this council included Walgreens, CVS, Cardinal, Walmart, McKesson, Rite Aid, and ABDC.

571. NACDS fought regulatory efforts to require Defendants to use available dispensing related data and red flags to prevent diversion, opposing "recent DEA actions in which the DEA is expecting pharmacists to be enforcement agents with respect to prescriptions for pain medications."

572. NACDS, Rite Aid, and Walgreens also sought to help their "business partners HDA" "kill" other controlled substance legislation.

573. Manufacturers were also able to participate in NACDS activities. For instance, in 2012, Endo sent around "NACDS Follow Up" notes regarding meetings with ABDC and a chain pharmacy distributor about SOM practices and the impact of DEA enforcement regarding Schedule II opioids on their business.

574. NACDS has continued to support the efforts of the National Retail Pharmacies to whitewash their role in creating and sustaining the opioid epidemic. In a recent amicus brief, NACDS asserted: "Although it is a commonly recognized that pharmacists and pharmacies were

not responsible for the crisis, NACDS members are doing their part to prevent the diversion of prescription medications, reduce drug abuse, and save lives."[168]

575. Taken together, the interaction and length of the relationships between and among the Manufacturing Associates and the Distributor Defendants reflect a deep level of interaction and cooperation between two groups in a tightly knit industry. Defendants operated as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

VI. THE OPIOID PROMOTION ENTERPRISE HARMED PLAINTIFF AND OTHER HOSPITALS.

576. As set forth above, St. Elizabeth is compelled to treat, and cannot turn away, patients with opioid-related conditions. Because of this obligation, St. Elizabeth cannot avoid the harm directly imposed by acts and omissions of the Opioid Promotion Enterprise.

577. The actions of the Opioid Promotion Enterprise expanded formularies, increased the number of OUD patient encounters and, ultimately, caused St. Elizabeth to suffer operational losses in the millions.

578. There are different categories of patients whose opioid use impacts hospital operations. Some patients may meet the diagnostic criteria for OUD. Other patients may have become physiologically and/or psychologically dependent on opioids without meeting the diagnostic criteria for OUD. Still others may present for care after a single episode of opioid use (e.g., an accidental overdose by an opioid-naïve patient). For most of these patients, their opioid use began with (and often was limited to) opioids that they were prescribed in accordance with Defendants' false narratives regarding the risks and benefits of opioids.

[168] Brief of the Nat'l Ass'n of Chain Drug Stores as *Amicus Curiae* in Support of Defendants' Motion to Dismiss, *United States v. Walmart Inc.*, No. 20-1744-CFC (D. Del. filed Mar. 3, 2021), https://corporate.walmart.com/media-library/document/2021-03-03-the-national-association-of-chain-drug-stores-nacds-amicus-brief/_proxyDocument?id=00000177-fe2b-def1-a37f-fefb01180000.

579. The care required by opioid-dependent patients may take the form of treatment to counter the immediate effects of the opioid use (e.g., administration of naloxone to reverse an opioid overdose), treatment of conditions brought about by the opioid use (e.g., care for infants with neonatal abstinence syndrome), or medication for OUD (e.g., daily doses of methadone or buprenorphine provided during a patient's hospital stay to ensure continuity of medication for OUD treatment).

580. However, opioid-dependent patients may also present with other sorts of conditions, the treatment of which may be affected by their opioid dependence. For instance, a patient who has been on a high regimen of prescription opioids for a long period of time may present for a gallbladder removal; or, the same patient may present in the emergency room with a traumatic injury following a vehicular accident. Care for these patients in the OUD-patient cohort will be more complex and will place a greater burden on the hospital's resources than care for an equivalent non-OUD patient cohort receiving the same treatment but without the history of opioid use.

581. Studies have shown that, "[c]ompared with opioid-naïve patients, opioid-tolerant patients will typically generate a greater workload for medical and nursing staff. . . . . They require more frequent consultations and prescription alterations."[169] "Opioid-dependent patients presenting for surgery will challenge a health care system to provide optimal patient care, requiring close communication among the surgical team, anesthesiologists, referring physicians, and pain

[169] GK Simpson & M Jackson, *Perioperative Management of Opioid-Tolerant Patients*, 17(4) BJA Education 124 (2017), https://www.bjaed.org/action/showPdf?pii=S2058-5349%2817%2930056-2; *see also* Joseph H. Donroe, et al., *Caring for Patients with Opioid Use Disorder in the Hospital*, 188 Can. Med. Ass'n J. 1232 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5135493/pdf/1881232.pdf ("The inpatient care of patient with opioid use disorder can be medically and psychosocially complex.").

specialists."[170] "The proportion of opioid-tolerant patients requiring acute pain management [e.g., in connection with surgery] has increased, often presenting clinicians with greater challenges than those faced when treating the opioid-naïve."[171] These include an "increased risk of awareness" and the concomitant need to take extra precautions to counteract that risk[172] as well as the need to monitor and respond to patients showing symptoms of opioid withdrawal.

582. Plaintiff must expend more resources to treat opioid-dependent patients, in comparison to patients with similar diagnoses who are not opioid dependent. When comparing the two cohorts, the ratio of payments received—including from private payors—to charges billed is lower for the opioid-dependent cohort. This operational impact coincides with the increase of opioids circulating in the community and increases in the population of opioid-dependent patients.

583. This is not just a matter of some patients not paying their bills. Instead, the financing mechanisms of modern healthcare set rates for types of treatment. If the same treatment for an individual patient becomes more complicated or expensive (as it does in patients with opioid dependency or OUD), then a healthcare provider's rate of realization declines.

584. For example, it is increasingly common for individuals with OUD to present at a hospital with endocarditis, treatment for which may involve surgery followed by intravenous antibiotic treatment. This treatment requires the installation of an IV port in the patient; typically, a patient with such a port will be released and will receive their intravenous antibiotics on an outpatient basis. However, because IV ports provide a ready route for intravenous drug use, the

[170] Klaus D. Torp & Robert L. McClain, *Perioperative Pain Control in the Opioid-Dependent Patient: Just Bite the Bullet?*, 10 Current Anesthesiology Reports 473 (2020), https://link.springer.com/article/10.1007/s40140-020-00425-2.
[171] C.A. Huxtable, et al., *Acute Pain Management in Opioid-Tolerant Patients: A Growing Challenge*, 39 Anaesthesia Intensive Care 804 (2011), https://journals.sagepub.com/doi/epdf/10.1177/0310057X1103900505.
[172] *Id.*

standard of care for patients with IV ports who have a concurrent OUD is to conduct the entire course of treatment on an inpatient basis, with an associated additional burden on the hospital's operations.

585. The structures by which medical care in hospitals is funded (generally by fixed fees for particular treatments) means that the operational impact of treating opioid-dependent patients cannot be passed along to patients or other payors. For example, if a floor nurse must visit an opioid-dependent patient staying in the hospital for some treatment eight times over the course of a shift to manage complications related to the patient's opioid use but would only have to visit an otherwise equivalent non-opioid-dependent patient four times over the course of the same shift, there is an impact on the hospital's operations. However, no funding mechanism for hospitals provides additional funding to account for the opioid-dependent patient's greater use of staff resources.[173]

586. During admission, hospital professionals routinely consult with patients to assess which medications the patients are taking at home. Due to Defendants' conduct, hospitals can no longer trust patients to self-report their prescriptions and must take additional steps to independently verify their patients' purchases (such as by examining the PDMP).

587. Additionally, individuals with OUD have presented and continue to present themselves to Plaintiff claiming to have illnesses and medical problems in order to obtain opioids. Plaintiff has incurred and continues to incur operational impacts related to the time and expense of identifying, diagnosing, testing, or otherwise attempting to treat these individuals.

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[173] *Cf.* Paul A. Taheri, et al., *Paying a Premium: How Patient Complexity Affects Costs and Profit Margins*, 229 Annals of Surgery 807 (1999), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1420827/pdf/19990600s00007p807.pdf (suggesting ways, in the trauma context, in which "it is the more medically complex cases that potentially compromise the economic position of the . . . institution").

588. Hospitals must also treat opioid users who present in need of emergency care, a fact of which Defendants were aware. This obligation arises under the Emergency Medical Treatment and Active Labor Act ("EMTALA"), 42 U.S.C. § 1395dd, which requires hospital emergency departments that accept payments from Medicare to provide care to anyone seeking treatment for a medical condition, regardless of citizenship, legal status, or ability to pay. Under EMTALA, participating hospitals may not transfer or discharge patients needing emergency treatment except with the informed consent or stabilization of the patient or when their condition requires transfer to a hospital better equipped to administer the treatment. Similarly, if a pregnant opioid-dependent person presents for treatment, under EMTALA, the hospital must provide care for both the opioid-dependent parent and the opioid-dependent baby.

589. This is no small burden. In 2017, an estimate 1.5 million emergency room visits were related to OUD.[174] Moreover, as with other patients, emergency care for opioid-dependent patients for any condition can be more complex than for similarly situated patients who are not opioid dependent.

590. Plaintiff has purchased and continues to purchase and administer opioids marketed and by Defendants. Plaintiff is a direct victim of Defendants' fraudulent and unlawful marketing, and of Defendants and the unnamed associates' alliances toward violating the CSA toward their mutual financial benefit. Plaintiff and other hospitals have used opioids as deceptively marketed by Defendants and have suffered damages as a direct and proximate result. Plaintiff would not have purchased the quantity of opioids it purchased had Plaintiff known the truth about Defendants' and the unnamed associates' false marketing scheme, i.e. that Defendants' claims

[174] Utsha G. Khatri, et al., Variation in Emergency Department Visit Rates for Opioid Use Disorder: Implications for Quality Improvement Initiatives, 51 Am. J. Emergency Med. 331 (2022).

regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded.

591. The financial impact on hospitals, including Plaintiff, includes, but is not limited to, the following:

a. operational losses suffered in connection with providing treatment to patients suffering from opioid-related conditions as the reason for presentation for care and/or as a comorbidity;

b. operational losses associated with patient counseling with respect to pain management, necessitated by overprescription to the general population and dissemination of false and misleading information to prospective patients and others; as hospitals and other providers question their patients' self-reporting, it necessitates that further steps be taken in all phases of diagnosis, treatment, and counseling;

c. the loss of revenue incurred by hospitals as a consequence of their obligation to provide care to patients suffering from opioid-related conditions;

d. costs of opioids purchased by hospitals themselves, which were direct targets of Defendants' and the unnamed associates' marketing campaigns;

e. costs of training personnel in the proper treatment of drug overdoses;

f. costs associated with training staff in the application of naloxone;

g. operational losses suffered in relation to infants born with opioid-related medical conditions or born dependent on opioids due to drug use by mothers during pregnancy, including the costs of creating and maintaining special facilities and costs associated with increased staffing to observe infant behavior and adjust doses of medication used to manage withdrawal symptoms;

h. operational losses associated with staff burnout, particularly in neonatal intensive care units, where staff suffer from PSTD, compassion fatigue, anger, addiction, and risk of suicide;

i. the expense of providing additional personnel to respond to security concerns created by patients and others suffering from OUD and other forms of opioid dependency;

j. the expense of purchasing and maintaining additional equipment necessitated by the increased demands placed on hospitals as a result of the increased population of opioid-dependent patients and the expanded services hospitals provided in response; and

k. costs of providing special programs over and above ordinary hospital services.

592. The Opioid Promotion Enterprise has caused a repeated and continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The harm is not completed, nor have all the damages been incurred until the wrongdoing ceases. Defendants' wrongdoing and unlawful activity have not ceased.

593. The harms suffered by Plaintiff and other hospitals were a direct and foreseeable result of the actions of the Opioid Promotion Enterprise. Defendants, as sophisticated participants in the pharmaceutical industry, knew that treatment provided to opioid-dependent patients would be provided by hospitals such as Plaintiff and that those hospitals' operations would be negatively impacted thereby.

VII. DEFENDANTS WERE MEMBERS OF THE OPIOID PROMOTION ENTERPRISE.

594. Defendants collaborated with one another and with other members of the Opioid Promotion Enterprise, including other manufacturers such as Endo, Purdue, and Mallinckrodt, Front Groups, KOLs, trade associations, and pill mills.

595. Defendants had a common objective, being to promote the manufacture, sale, distribution, dispensing, and use of prescription opioids. Defendants had a meeting of minds and entered into an agreement on this common object. They had a common interest in this purpose, as each profited from the sale of opioids and the conspiracy and actions were aimed to further their mutual financial benefit.

596. Defendants turned a blind eye to the misconduct of the other members of the Opioid Promotion Enterprise in order to allow that misconduct to achieve their common purpose.

597. As described above, Defendants used the PCF, the HDA, and NACDS for the activities of the Opioid Promotion Enterprise.

598. Funding KOLs and Front Groups allowed Defendants and the unnamed associates to pool their resources to promote mutually beneficial propaganda about the benefits and risks of prescription opioids to treat chronic, noncancer pain.

599. KOLs supported by Defendants and unnamed associates included:

a. Kathy Foley (Cephalon, Janssen, Purdue)

b. Lynn Webster (Teva, Cephalon, Endo, Purdue, Mallinckrodt)

c. Perry Fine (Cephalon, Janssen, Endo, Purdue)

d. Russell Portenoy (Cephalon, Janssen, Endo, Abbott, Purdue)

e. Charles Argoff (Teva, Janssen, Endo)

f. Scott Fishman (Janssen, Endo, Abbott, Mallinckrodt, Purdue)

g. Steven Stanos (Janssen, Endo, Abbott)

h. Paul Arnstein (Janssen, Mallinckrodt)

i. Kenneth Jackson (Endo, Purdue)

600. Front Groups financially supported, directed, and/or controlled by multiple Defendants and/or unnamed associates included:

a. APF (Cephalon, Teva, Janssen, Endo, Purdue, Abbott)

b. AAPM (Cephalon, Teva, Janssen, Endo, Allergan, AbbVie, Purdue)

c. APS (Janssen, J&J, Endo, Purdue, Abbott)

d. AGS (Janssen, J&J, Endo)

e. AfPA (Cephalon, Teva, J&J, Endo, AbbVie, Mallinckrodt, Purdue)

f. ACPA (Cephalon, Teva, Janssen, Endo, AbbVie, Mallinckrodt)

g. NPC (Teva, J&J, Allergan, Mallinckrodt, Purdue)

601. Trade Associations patronized by Defendants and multiple unnamed associates included:

a. PCF (Cephalon, Teva, J&J, Endo, Actavis, Abbott, Purdue, Grünenthal, ABDC (through HDA), Cardinal (through HDA), Hikma (through HDA), McKesson (through HDA), H.D. Smith (through HDA), Schein (through HDA), CVS (through NACDS), Walgreens (through NACDS), Walmart (through NACDS), Kroger (through NACDS), Albertsons (through NACDS), Publix (through NACDS), Giant Eagle (through NACDS))

b. HDA (Teva, J&J, Endo, Hikma, Indivior, Mallinckrodt, Purdue, Cardinal, ABDC, McKesson, H.D. Smith, Schein)

c. NACDS (Walgreens, CVS, Walmart, Kroger, Albertsons, Publix, Giant Eagle)

602. Publications, websites, and CMEs developed and supported by multiple Front Groups, Defendants, and unnamed associates included:

a. *Responsible Opioid Prescribing* (Cephalon, Endo, Purdue, and FSMB)

b. *Treatment Options: A Guide for People Living with Pain* (Cephalon, Purdue, APF)

c. *Exit Wounds* (Endo, Purdue, APF)

d. *Guidelines for the Pharmacological Management of Persistent Pain in Older Persons* (Endo, Janssen, Purdue, AGS, APF)

e. *Pain Action Guide* (Endo, APF)

f. *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia* (Endo, NIPC)

g. *Special Considerations: Pain in Specific Populations* (Janssen, APF)

h. *Painknowledge.org* (Endo, APF, NIPC)

i. *Finding Relief: Pain Management for Older Adults* (Janssen, AAPM, AGS)

j. *Let's Talk Pain* (Janssen, APF)

k. *Partners Against Pain* (Purdue, CVS, APF)

l. *A Policymaker's Guide to Understanding Pain & Its Management* (Purdue, APF)

m. *Overview of Management Options* (Purdue, Endo)

603. In addition, Defendants and unnamed associates engaged in a variety of collaborative activities to support the excessive use of opioids, including:

a. Abbott and Purdue engaged in the co-promotion of OxyContin to physicians working in hospitals.

b. Janssen and Purdue agreed not to disparage one another's products or ineffective anti-diversion practices even though they knew that these strategies were driving excessive use and abuse of prescription opioids. Janssen's employees were specifically instructed not to "advance language that would attack a competitor's product" in order to avoid raising concerns about opioid misuse that would damage the entire market, including Janssen's share.

c. Janssen and Purdue worked together on a joint marketing effort called "Project Pearl," which including marketing for Ultram.

d. Janssen licensed, sold, and aggressively marketed Grünenthal's opioids: tramadol and tapentadol.

e. Cephalon, Purdue, Endo, and Mallinckrodt provided funding to FSMB to distribute pro-opioid materials.

f. Grünenthal provided the technology for ADF versions of Purdue's OxyContin and Endo's Opana and defended the effectiveness of that technology despite evidence to the contrary.

g. McKinsey worked with Purdue, Janssen, Endo, and Mallinckrodt to devise strategies to increase the sales of their prescription opioids and the market for prescription opioids generally.

h. McKinsey worked with ABDC to increase its sales of generic prescription opioids.

i. ABDC provided marketing assistance to Endo, Janssen, and Purdue to encourage pharmacies to order and dispense larger quantities of prescription opioids.

j. Teva and ABDC worked together through ABDC's Xcenda subsidiary to publish scientific articles promoting the use of opioids and minimizing their risks.

k. Cardinal provided marketing assistance to Allergan, Endo, Janssen, and Purdue to promote their prescription opioids.

l. McKesson provided marketing assistance to Allergan, Janssen, and Purdue to promote their prescription opioids.

m. Anda and H.D. Smith provided or agreed to provide marketing assistance to AbbVie in marketing Vicodin.

n. ABDC and Cardinal agreed to give Walgreens favorable treatment in their SOM programs, thereby enabling Walgreens pharmacies to place and have filled suspicious orders that should have been halted, investigated, and not shipped.

o. Cardinal and McKesson agreed to give CVS favorable treatment in their SOM programs, thereby enabling CVS to place and have filled suspicious orders that should have been halted, investigated, and not shipped.

p. Walgreens assisted Purdue in marketing OxyContin by allowing Purdue to have input into Walgreens's dispensing policies and by requiring its pharmacists to view "educational" material provided by Endo.

q. Mallinckrodt assisted Walgreens in shifting its controlled-substance distribution immediately to Cardinal following warnings and subpoenas issued to Walgreens's Perrysburg, Ohio distribution center.

r. Walgreens worked with Cardinal and ABDC to develop contingency plans to maintain the high supply of opioids to its pharmacies in the event that Walgreens lost its license to distribute Schedule II substances from its Jupiter, Florida DC.

s. In 2013, Walgreens entered a ten-year agreement with ABDC.[175] ABDC was described as able to gain "purchasing synergies" from Walgreens through the companies' relationship. According to ABDC's most recent 10-K, Walgreens now accounts for 33% of AmerisourceBergen's revenue.[176]

t. CVS worked with Purdue to disseminate the false message that the risk of addiction and potential for abuse associated with opioid use were very small. CVS allowed Purdue to train CVS's pharmacists with Purdue's promotional materials on OxyContin, which contained misrepresentations about the risks of using opioids.

u. CVS entered an agreement with Endo to promote, market, and advertise Endo's opioid products to consumers. CVS took on key responsibilities in marketing Endo's opioids to patients, including sending letters to targeted patients' homes, in order to increase patient adherence to continued use of opioids.

[175] As a part of its distribution agreement, Walgreens gained purchase rights to ABDC equity, allowing it to further participate in the prescription opioid shipment boom in America. Walgreens subsequently exercised these purchase rights, ultimately owning approximately 28% of ABDC. As part of the transaction, Walgreens can nominate up to two members of ABDC's Board of Directors. Currently, Walgreens's Co-Chief Operating Officer sits on the ABDC Board.

[176] AmerisourceBergen Corporation, *Form 10-K* (Nov. 19, 2020), https://d18rn0p25nwr6d.cloudfront.net/CIK-0001140859/44edc41e-d63c-4a49-81ce-619723b2ee77.pdf.

v. CVS worked with Cardinal to create programs that offered rebates and off-invoice discounts on Actavis's opioids in order to promote and increase sales of these opioids.

w. Walmart and Purdue worked together as early as 1995 to launch pro-opioid presentations featuring KOLs to pharmacists across the country.

x. Walmart marketed Actavis's Kadian.

y. Walmart and McKesson formed ClarusOne Sourcing Services LLP in 2016 to source generic pharmaceuticals and provide strategic sourcing services.

z. Purdue sought to persuade Walgreens that pharmacists who were calling to verify prescriptions five to six times a week were "overzealous" and "calling too much."

aa. Indivior cooperated with Walmart, Walgreens, and CVS to increase Suboxone film prescription rates through strategically negotiating agreements and pharmacist education programs. Through its "Here to Help" program, Indivior drove higher prescription rates for other manufacturers by directing patients with OUD to doctors known to improperly prescribe opioid products. And Indivior cooperated with Purdue in its legislative lobbying efforts.

bb. Albertsons promoted opioid manufacturers' products in its stores and pharmacies, like Butrans.

cc. Kroger marketed and promoted Purdue's products in its stores, and it circulated Purdue's continuing education programs among its pharmacists.

dd. Indivior worked with Walmart, Walgreens, and CVS to design systems that would increase the sales of Suboxone.

ee. Publix participated in rebate programs with Mylan, Actavis, Par, Endo, and Mallinckrodt.

ff. Giant Eagle participated in rebate programs with Actavis, Par, Endo, Qualitest, and Purdue.

604. Defendants and the Distributor Defendants and the Manufacturing Associates collaborated on common approaches to their CSA obligations. This began with Purdue, who explained that manufacturers could not solve the DEA problem on their own: "The responsibility for making the decision to ship rests with the supplier. . . . That is why we must collaborate." For Defendants, it was important to "pledge to remain in close contact with each other whenever there

may be a questionable order" in order to "protect ourselves and our registrations regarding suspicious order discovery and reporting." This was aimed at avoiding interruptions in the supply chain.

605. Examples of these collaborated activities include, e.g., Mallinckrodt noted that half of the flagged orders in its SOM system were from the Big 3 and that a "significant amount" were from Walgreens, Walmart, and CVS, but decided, in order to protect these sales, not to treat these orders as suspicious.

606. In 2013, Endo met with CVS and Cardinal to discuss SOM systems.

607. In July 2013, Purdue met with ABDC, McKesson, Cardinal, and H.D. Smith as well as Walgreens, Walmart, and Rite Aid to discuss SOM issues such as DEA actions and thresholds.

608. In 2014, McKesson noted that it had met with its "manufacturing partners," including "Mallinckrodt, Purdue, and Actavis," to "share with them our controlled substance monitoring information and identify opportunities for collaboration," and had further met with CVS to review SOM systems.

609. Distributors also conspired with the National Retail Pharmacies in order to undermine the goals of the CSA to prevent diversion of dangerous controlled substances.

610. Cardinal turned a deliberate blind eye to Walgreens's orders, claiming to rely on Walgreens's SOM program. Prior to 2012, however, Walgreens had no SOM program for orders to outside Distributors, and thus did not monitor its pharmacies' orders to Cardinal, even if Walgreens itself had cut that pharmacy off for self-distribution. Cardinal allowed Walgreens access to its thresholds and provided Walgreens early warnings at 75% of threshold. Cardinal helped Walgreens to time orders to avoid hitting SOMs reporting triggers and provided Walgreens with advance notice of due diligence site visits to Walgreens stores. When Cardinal identified a

Walgreens store with suspicious orders, rather than report to the DEA, Cardinal would pass the store to the Walgreens corporate office to determine appropriate follow up. Cardinal notified Walgreens when it intended to stop distribution to a Walgreens store, so that Walgreens could secure other vendors to provide product to that store and could instruct the store not to place additional orders with Cardinal that would have to be reported to the DEA.

611. Cardinal gave its "proxy" to CVS headquarters to perform due diligence investigations of potentially suspicious orders and individual CVS pharmacies that were ordering excessive amounts of prescription opioids. Cardinal turned a deliberate blind eye to that fact that CVS's "sophisticated internal" SOM program, on which Cardinal claimed to rely, was really a theft report without any SOM capabilities. Cardinal also contracted with CVS to permit it to set its own threshold quantities for controlled substances at "any value CVS deems appropriate." CVS and Cardinal Health agreed not to disrupt CVS business, even if an order was flagged. Cardinal Health ignored that CVS had no policies, procedures, or programs to monitor prescription opioid orders placed by its pharmacies to Cardinal or any other outside vendor until at least 2014. Rather than report suspicious CVS orders to the DEA, Cardinal generally alerted CVS and continued to ship. Even when Cardinal identified "consistent… growth of controlled substances … across CVS Chain stores," "unusual" ordering, and stores with opioid orders that were thousands of percentage points higher than previous months, Cardinal relied on CVS's assessment that there was "no evidence of controlled substance diversion" and continued to "ship controlled substances to these pharmacies." Cardinal alerted CVS to states in which the "DEA and states are aggressive" and might scrutinize the significant increases. Even after the DEA's 2012 regulatory action against Cardinal, CVS and Cardinal conspired to avoid reporting suspicious orders through the "Early Dialogue" process, which provided CVS an early warning at 75% of the threshold limit so CVS

could request a threshold increase or delay orders to the next cycle. Cardinal readily granted threshold increases and overrides for CVS without appropriate due diligence.

612. In turn, CVS issued internal instructions to not report to the DEA any orders placed to an outside vendor (like Cardinal), even "order[s] deviating from the normal size, frequency, and/or buying pattern and deem the order to not be for legitimate purposes . . . ." In addition to shipping to CVS stores, Cardinal Health also distributed directly to CVS warehouses, which in turn distributed directly to CVS stores. The distributions from Cardinal to CVS warehouses, termed "brokerage sales," were not included in Cardinal's SOMs process and did not have set thresholds as other sales did. These orders were not monitored despite the fact that through these orders CVS was ordering so much hydrocodone that it was "able to strip hydrocodone inventory from Cardinal."

613. When ABDC identified Walgreens stores or orders that raised a "concern" with regard to oxycodone, ABDC and Walgreens conspired to avoid reporting to the DEA. ABDC stated: "I'm trying to think of everything we can do to prevent having a bunch of orders reported to [the] DEA and held." Despite DEA guidance that "a suspicious order placed by a customer pharmacy is made no less suspicious by application of a system designed to reduce or eliminate such orders prior to shipping," ABDC and Walgreens decided to have Walgreens "police their own orders and block any order to [ABDC] that would exceed AB[D]C's threshold thus triggering a suspicious order being sent to [the] DEA from AB[D]C." Requests to clear orders or raise thresholds, however, were almost always approved, as evidenced by the 95%+ approval rate for FY 2014 and 2015.423

614. When orders "outside the expected usage" made it to ABDC, ABDC and Walgreens set up meetings to discuss adjusting thresholds or using "soft blocking." Contrary to DEA guidance

and ABDC's stated policy, ABDC provided Walgreens with the threshold limits set in ABDC's order monitoring program, and also provided Walgreens with weekly SOM statistics. ABDC generally would not take action on Walgreens' orders that exceeded its thresholds without talking to the Walgreens integrity team.

615. CVS conspired with McKesson to keep the drugs flowing and avoid reporting to the DEA. McKesson gave CVS early threshold warnings at 60% of their assigned Schedule II thresholds to provide "plenty of notice" before a SOM event would occur, so that "high volume" purchasers of Schedule II substances could have their thresholds increased accordingly. McKesson routinely increased opioid thresholds for CVS without adequate due diligence. McKesson did not require CVS to provide store level data, but essentially allowed CVS to set its own thresholds. In violation of its internal policy (and DEA requirements) not to increase thresholds without a documented reason, McKesson provided automatic increases. McKesson abdicated its due diligence duties to CVS, relying on CVS to investigate its own suspicious orders, and allowing CVS act as its "proxy in regards to regulatory oversight." McKesson also did not require CVS to provide storewide ordering data. McKesson essentially allowed CVS to monitor itself, despite the fact that CVS had no suspicious order monitoring process relating to McKesson until 2014. CVS also internally stated that it would not report to the DEA suspicious orders placed to McKesson, even where CVS knew the orders "deviating from the normal size, frequency, and/or buying pattern and [were] deemed to not be for a legitimate purpose or are at risk of being diverted." Even when McKesson identified suspicious activity, it did not stop shipping nor did it make any report to the DEA. In 2012, McKesson identified 93 CVS pharmacies that were of "concern" because of oxycodone ordering patterns, but McKesson kept shipping and did not report to them.

616. McKesson provided daily updates to Giant Eagle and Walmart when they were approaching McKesson's controlled substance ordering thresholds. McKesson employees often follow up these automated messages with emails that sometimes solicited requests to increase the approaching thresholds.

617. Although some Defendants have ceased engaging in some of the conduct alleged in this Complaint (e.g., by discontinuing certain opioid products), the Opioid Promotion Enterprise is ongoing. No Defendant has tried to leave the enterprise and indeed, Defendants continue to forward the goals of the enterprise by, among other things, making false statements concerning their historical record and current practices of compliance with their duties to prevent excess use and diversion of prescription opioids.

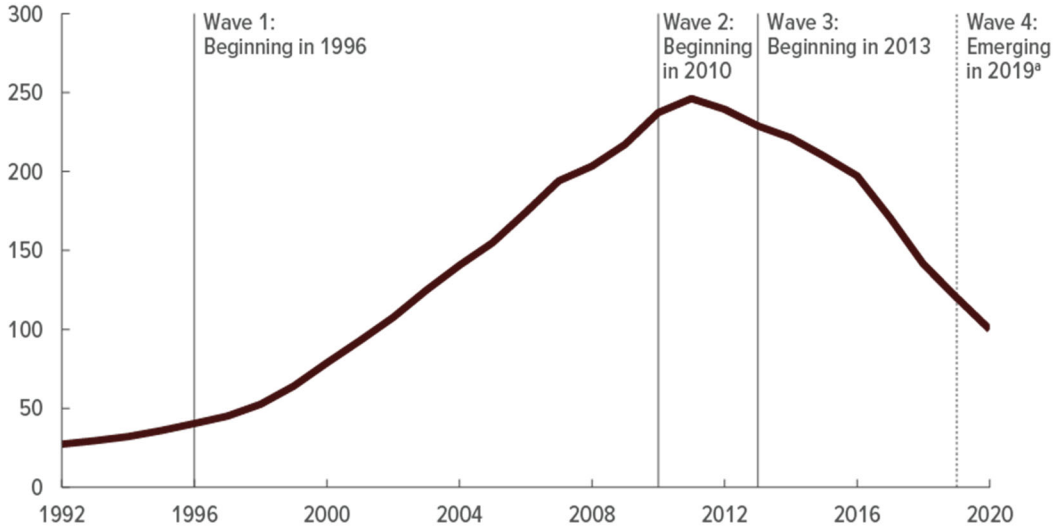
618. Defendants' conduct was not merely parallel; Defendants actively chose to support one another.

619. Not all of the coordinated conduct described in this Complaint was unlawful, but taken together, it establishes that Defendants reached agreements, had a meeting of the minds, and had ample opportunity to collaborate on the predicate acts described below. This sheer extent and continuity of conduct over a period of many years allows the inference that Defendants, along with the KOLs, Front Groups, trade associations, and pill mills were part of the Opioid Promotion Enterprise.

VIII. THE OPIOID CRISIS IS NOT OVER.

A. Continued Prescriptions and Overdoses

620. Opioid prescriptions in the United States are still far too high. Opioid prescriptions (in total dosage units) are much higher than they were before the Defendants' marketing blitz began.



Source: Congressional Budget Office[177]

621. In fact, MMEs per capita prescribed in 2020 in the United States were 334 per person -- more three times as high as they were in 1992 (106 per person).[178] Prescribing practices have improved from the peak of prescription rates in or around 2011 (well over 700 MME per person), but they have a long way to go to return to the baseline levels existing before Defendants changed the national narrative on opioid prescribing.

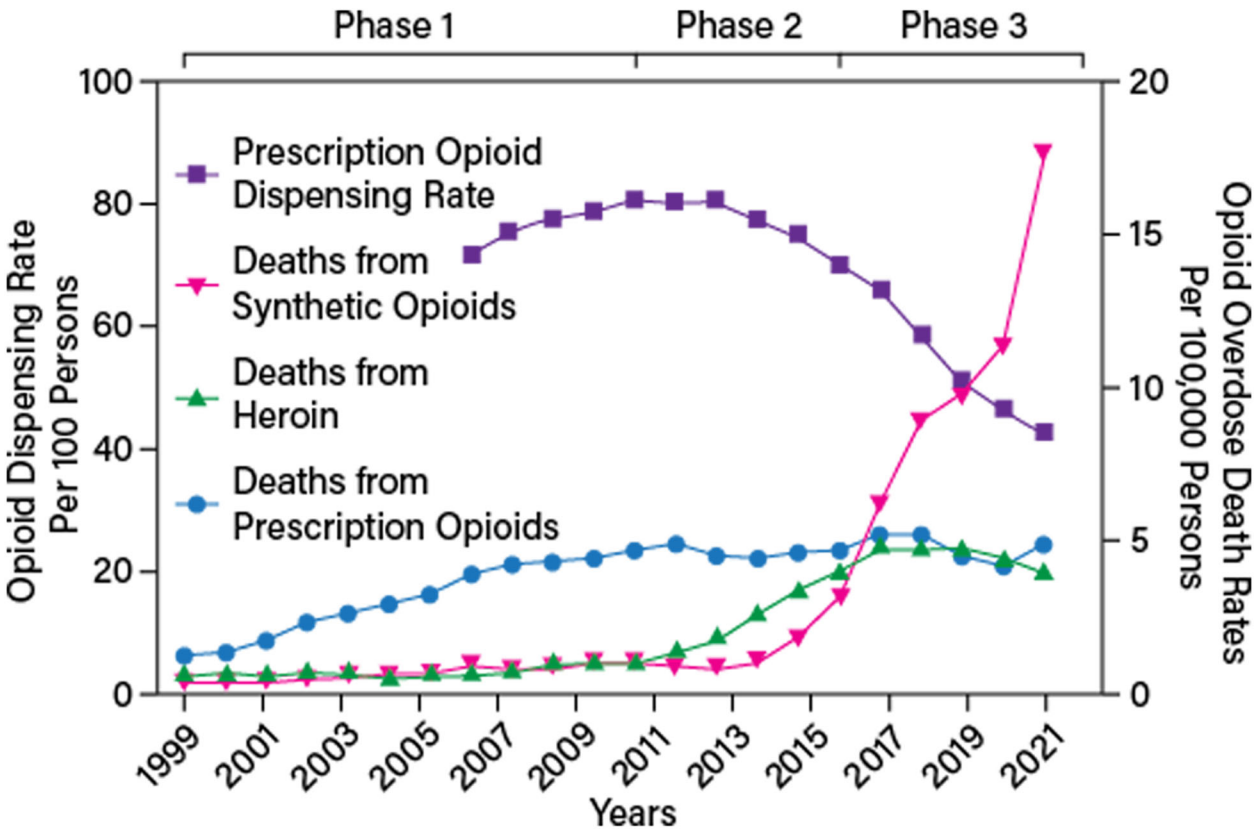
622. Opioid prescription rates in the United States are still considerably higher than those in other developed countries. In fact, "[t]he amount of prescription opioids dispensed per million people per day in the United States is approximately four times the median for member countries of the Organization for Economic Co-operation and Development."[179]

623. No doubt, opioid prescriptions in the United States are down from their peak in the early 2010s. This is partly due to changes in prescribing and distribution behavior. But part of this

[177] Congressional Budget Office, "The Opioid Crisis and Recent Federal Policy Responses" (Sept. 2022), https://www.cbo.gov/publication/58532.
[178] Johanna Catherine Maclean, et al., "The Opioid Crisis, Health, Healthcare, and Crime: a Review of Quasi-Experimental Economic Studies," National Bureau of Economic Research (Apr. 2022), https://www.nber.org/system/files/working_papers/w29983/w29983.pdf
[179] Congressional Budget Office, "The Opioid Crisis and Recent Federal Policy Responses" (Sept. 2022), https://www.cbo.gov/publication/58532.

decline is also due to the appearance of competing products – specifically, increased supply of heroin and fentanyl.

624. Opioid deaths are still increasing. Even when the data is limited just to prescription opioids, death rates are still climbing, although they appear to be hitting a plateau. In any event, they certainly have not started declining in any meaningful way. Overall opioid deaths are skyrocketing.



Data limited to the United States. Source: American Institute of Chemical Engineers (2022).[180]

[180] Benjamin Haslund-Gourley, et al., "Responding to the Opioid Epidemic," American Institute of Chemical Engineers (Sept. 2022), https://www.aiche.org/resources/publications/cep/2022/september/responding-opioid-epidemic.

625. While most deaths are now attributed to fentanyl and other synthetics (primarily distributed illegally), many of the persons using these products got their start, and developed their dependency, with prescription opioids.

B. Continued Activity of Front Groups and KOLs

626. Defendants and some unnamed associates may not be expressly promoting specific products through direct marketing channels as they did in the past, but the perpetuation of the same false narrative continues, and Defendants and their allies continue to vigorously resist efforts to undo the effects of their fraudulent marketing.

627. In March 2016, the Centers for Disease Control issued its new opioid guidelines (the "2016 Guidelines") urging doctors to limit prescriptions and, when possible, opt for non-opioid alternatives. For the first time, a respected agency was saying that the risks of painkillers greatly outweighed the benefits for the vast majority of chronic pain patients" "If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids."

628. There was immediate pushback to the 2016 Guidelines by members of the Opioid Promotion Enterprise, and the vigorous debate continues to this day.

629. Many of the pro-opioid advocates spread false depictions of the 2016 Guidelines, such as portraying them as opposing mandatory limitations, when the truth is they are merely guidelines for best practices. The pro-opioid groups also maintain a narrative that the 2016 Guidelines imposed mandatory dosage reductions (or "forced tapering") of all patients presently receiving opioid prescriptions, which is also a complete falsehood. No one engaged in the national dialogue on opioids favors such a measure. They argue that opioid prescribing is no longer an issue since most deaths are now among patients taking illegally manufactured and distributed products, but they ignore the hard fact that deaths from legal prescription opioids have merely leveled off

and have *never* declined, as well as the fact that prescription opioids have similar effects as their illegally manufactured counterparts and can serve as a gateway drug.

630. Perhaps the most outspoken of the present-day KOLs is Dr. Stefan G. Kertesz, an internist in Birmingham, Alabama, and associate professor at the University of Alabama. Kertesz was one of the two "experts" (along with Dr. Daniel Alford, of the School of Medicine at Boston University) on a "[a] multidisciplinary expert panel" formed by the AAPM, a notorious Front Group, to meet and "review the influence of the core recommendations of the guideline on pain management practices, principally regarding the estimated 5 to 8 million Americans with chronic pain currently on opioids."[181] In March of 2019, Kertesz was a lead author (along with four other physicians, including Alford) on a letter calling on the CDC to reiterate that its 2016 Guidelines were recommendations and were not binding. Kertesz and his allies have raised their concerns in both popular and academic publications as well as at various medical conferences. For instance, he co-authored an article published by STAT entitled "Strict limits on opioid prescribing risk the 'inhumane treatment' of pain patients."[182]

631. The Washington Legal Foundation, a pharma-aligned group, opposed the 2016 Guidelines, saying the lack of disclosure was a "clear violation" of federal law. The Academy of Integrative Pain Management ("AIPM") (formerly the AAPM), a longstanding PCF participant, went so far as to ask congressional leaders to investigate how the CDC had developed the guidelines and a House committee asked the CDC to turn over documents about its advisors.

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[181] Kroenke K, Alford DP, Argoff C, Canlas B, Covington E, Frank JW, Haake KJ, Hanling S, Hooten WM, Kertesz SG, Kravitz RL, Krebs EE, Stanos SP, Sullivan M. Challenges with Implementing the Centers for Disease Control and Prevention Opioid Guideline: A Consensus Panel Report. Pain Med. 2019 Apr 1;20(4):724-735, 725. doi: 10.1093/pm/pny307. Erratum in: Pain Med. 2022 Aug 31; 23(9):1636. PMID: 30690556.

[182] Kertesz, SG and Gordon, AJ. "Strict limits on opioid prescribing risk the 'inhumane treatment' of pain patients." STAT. Feb. 24, 2017, https://www.statnews.com/2017/02/24/opioids-prescribing-limits-pain-patients/ Last viewed Sept. 23, 2022).

632. Many KOLs presently and formerly associated with industry-supported front groups were outspoken against the 2016 Guidelines. Some had managed to participate in federally created advisory panels on pain management, such as the Interagency Pain Research Coordinating Committee (the "IPPCC") a 19-member panel coordinating pain research that had been created by the NIH in 2010. Industry-aligned participants included Richard Payne, a former APF board member, who questioned whether the experts advising the CDC had "conflicts of interests in terms of biases, intellectual conflicts that needed to be disclosed." They also included Myra Christopher, whose organization received funding from opioid drugmakers.

633. In 2016, after the adoption of the 2016 Guidelines, the industry (including Endo and the HDA) spent heavily lobbying for the legislation to create the Pain Management Best Practices Inter-Agency Task Force, a task force to review and update best practices on pain management and painkiller prescribing. Many of the task force members had ties to the opioid industry.

634. Many Front Groups historically funded by the Defendants remain quite active in advocating against more restrictive prescribing practices. This includes the U.S. Pain Foundation ("USPF") and the American Chronic Pain Association, both funded by Janssen, Purdue and others. The USPF's President could be seen at what was ostensibly a "pro-patient" rally at Brandeis University in Waltham, Massachusetts on October 25, 2023, seeking the termination by the university of Andrew Kolodny, a professor and longtime advocate for more restrictive opioid prescribing practices. The Denver-based RADARS program created by Purdue back in 2001 also remains very active in pro-opioid advocacy and continues to argue against stricter limitations on prescription opioids before multiple legislatures and federal agencies.

635. The pro-opioid advocacy movement has had some successes, such as the CDC's decision in 2022 to modify the 2016 Guidelines so as to clarify that they did not impose maximum daily dose of 90 MMEs (an extraordinarily high daily dosage). To be clear, the 2016 Guidelines never set a hard ceiling at 90 MME daily, although they were often falsely portrayed as doing so.

636. The false narrative conspiracy never ended. None of the Defendants have ever renounced the narrative they created, and which persists, nor have they taken any steps to affirmatively distance themselves from the conspiracy behind this narrative.

IX. COLLECTIVE CONDUCT ALLEGATIONS

A. Conspiracy Allegations

637. Defendants conspired to engage in the wrongful conduct complained of herein and intended to benefit both independently and jointly from their wrongful conduct.

638. On December 16, 2020, the Senate Finance Committee issued the findings in its most recent report, which were summarized as follows:

> Our work reveals that opioid manufacturers have maintained extensive financial relationships with tax-exempt organizations, including pain advocacy groups, professional provider groups, and medical associations. In turn, these groups have sought to influence opioids prescribing practices and related Federal policy connected to opioid use and pain care that directly affects Medicare and Medicaid.[183]

639. Manufacturing and Distributor unnamed associates agreed among themselves to increase the supply of opioids and fraudulently increase the quotas that governed the manufacture and supply of prescription opioids. Manufacturing and Distributor unnamed associates did so to increase sales, revenue, and profit from their opioid products. Defendants were active and co-conspirators and coordinators of that unlawful conduct.

[183] December 2020 Senate Bipartisan Opioids Report, *supra*, at 2.

640. The interaction and length of the relationships between and among Manufacturing and Distributor unnamed associates and Defendants herein reflects a deep level of interaction and cooperation in a tightly knit industry. Those unnamed associates and Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

641. Those entities utilized their membership in the Healthcare Distribution Alliance and NACDS and other forms of collaboration to agree to a common approach to their duties under the CSA to report suspicious orders, increase opioid distribution, dispensing, and demand, and, related thereto, achieve a mutual financial benefit. Defendants and the unnamed associates overwhelmingly agreed on the same approach – to refuse to effectively identify, report, or halt suspicious opioid orders and so to fail to prevent diversion, and unlawfully dispense opioids. They agreed to restrict reporting to insulate the entire industry from scrutiny. Defendants and those unnamed associates acted unlawfully, failing their obligations under the CSA and other applicable law. Defendants were aware, both individually and collectively, of the suspicious orders flowing from their facilities, and improper dispensing therefrom.

B. Joint Enterprise Allegations

642. Defendants entered into an agreement with respect to opioids and/or distribution of opioids in the Region and in Plaintiff's communities.

643. The agreement had a common purpose: to promote the sale and distribution of opioids through the marketing of opioids and/or distribution of opioids into the Region and into Plaintiff's communities, in violation of state common law, statutes, and regulations.

644. Defendants had a community of pecuniary interest in that common purpose, as all of the Defendants profited from sales of opioids in the Region. Defendants associated with each other and the co-conspirator unnamed associates in the RICO predicate acts complained of herein,

sharing the common goals and purposes and through the procedures and systems to coordinate the group's activities as detailed herein.[184]

645. Defendants had an equal right to a voice in the direction of the enterprise.

X. TOLLING AND FRAUDULENT CONCEALMENT

646. Defendants, individually and acting through their employees and agents, knowingly and intentionally concealed material facts and knowledge from Plaintiff and others to induce them to purchase and administer opioids as set forth in detail above.

647. Defendants invented the term "pseudoaddiction" and promoted it to the medical community, including to Plaintiff. Defendants provided the medical community, including Plaintiff, with false and misleading information about ineffectual medical strategies to avoid or control opioid addiction. Manufacturer Associates recommended to the medical community that dosages be increased, while concealing the risks of doing so. Defendants and the unnamed associates spent millions on a misinformation campaign highlighting opioids' alleged benefits and disguising their risks. Defendants further misrepresented and concealed from Plaintiff their avoidance and failures of their CSA obligations.

648. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addition and death; in falsely promoting abuse-deterrent formulations as reducing abuse; in falsely claiming that OxyContin provides 12 hours of relief; in falsely portraying their efforts or commitment to rein in the supply and diversion of opioids; and doing all of this while knowing full well that their statements were misrepresentations of facts material, Defendants have engaged in intentional, fraudulent misrepresentations and concealment of the material fact.

[184] *See supra* n.3, indicating Defendants are not now required to answer the specific RICO allegations of this paragraph within the bellwether, Track 23.

649. Defendants intended that Plaintiff would rely on their misrepresentations, omissions, and concealment, knew that Plaintiff would rely on their misrepresentations, and knew that such reliance would cause harm to Plaintiff. The medical community, including Plaintiff, were duped by Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing.

650. Plaintiff reasonably relied on Defendants' misrepresentations in dispensing Defendants' opioids. The use of Defendants' opioid medicines became widespread and continuous as a result.

651. The continued tortious and unlawful conduct by Defendants has caused a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The harm is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants have not ceased. The nuisance created by Defendants remains unabated.

652. Plaintiff's claims are equitably tolled because Defendants knowingly and fraudulently concealed the facts, their wrongful acts, and the material information needed to discover those acts. As a result of Defendants' conduct, Plaintiff did not know and could not have known through the exercise of reasonable diligence, of its claims.

653. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result, Plaintiff, without any fault or lack of diligence on their part, was unable to obtain vital information bearing on its claims.

654. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from the improper acts and omissions of Defendants. They do not seek damages which may have been suffered by individual citizens for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of Defendants.

655. Plaintiff suffered actual pecuniary damages and special injury proximately caused by Defendants concealment of material fact, which include but are not limited to an increase in OUD patient encounters which resulted in increased charges (for more treatment) with fewer payments recouped; increased resources directed toward emergency services, emergency response, additional training, additional security; and, physical and emotional fatigue and distress stemming from the relentless cycle of encounters with opioid use disordered patients.

656. Plaintiff presently lacks the operational resources necessary for implementing strategies to abate the consequences of Defendants' misconduct. To mitigate and reduce harm caused by the Defendants to the Plaintiff, the nuisance of opioids experienced by the Hospitals must be addressed with specific tactics, equipment, staff and programming.

657. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a hospital would reasonably expect to occur and is not part of the normal and expected operational expenditures for a hospital's existence. Plaintiff alleges wrongful acts which were neither discrete nor of the sort a hospital can reasonably expect.

XI. CAUSES OF ACTION

COUNT I

Civil Conspiracy

658. Plaintiff repeats, realleges, and incorporates by reference paragraphs 1 to 610 of this Complaint, as if fully set forth herein.

659. Plaintiff brings this claim under the common law providing for the civil liability of persons who conspire to commit one or more unlawful or tortious acts.

660. As detailed in this Complaint, Defendants committed unlawful and/or corrupt combinations of actions, through express or implied agreements, to engage in concerted actions to perpetuate unlawful acts. The unlawful acts committed by Defendants further to this conspiracy include without limitation the violation of the CSA and RICO act.[185]

661. Conspirators are liable for any tortious act, even unknown, committed in furtherance of the conspiracy, including acts not personally committed.

662. All named Defendants conspired with each other and with various entities and persons who are not named in this Complaint to commit the acts upon which each of the claims alleged in this action are based. At the core of the conspiracy was a meeting of the minds on an object to be accomplished. The goals of the conspiracy, that is, the gist of the conspiratorial meeting of the minds, was to expand the market for and supply of opioids, and to accomplish this, Defendants falsely marketed opioids and failed to control against diversion in the face of overwhelming evidence that diversion was taking place.

663. Even if some of the Distributor Defendants were competitors with each other in some spheres of business, or some of the Manufacturing Associates were competitors with each other, or some of the National Retail Pharmacies were competitors with each other, it served all of their interests to promote opioid use, to sell as many opioids as possible, to create a marketplace where massive distribution and use of and addiction to opioids was the norm, and to look the other way and fail to report or control massive drug diversions against overwhelming evidence of the

[185] *See supra* n.3, indicating Defendants are not now required to answer the specific RICO allegations of this paragraph within the bellwether, Track 23.

epidemic they were creating. They acted in concert and in tacit and explicit agreement to pursue these goals, which included committing these acts for their mutual financial benefit.

664. Each Defendant is liable for its co-conspirators' acts in furtherance of the conspiracy.

665. Each of the Claims for Relief asserted in this Complaint arises from acts in furtherance of the conspiracy described in this Complaint and in this Count, and each Defendant is liable for the conduct of its co-conspirators in the commission of those torts and/or statutory violations.

666. Defendants' conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against its commercial interests in not reporting the unlawful distribution and dispensing practices of their competitors to the authorities when under a legal duty to do. Each Defendant acted against its commercial interests in this regard due to an actual or tacit agreement between Defendants that they would not report each other to the authorities so they could all continue to engage in their unlawful conduct.

667. Defendants had a meeting of the minds on the object of the course of action for this conspiracy. Defendants knew and agreed upon the unlawful object or course of action for this conspiracy. Defendants also knew that their wrongful actions would inflict injury upon the targets of the conspiracy, including Plaintiff.

668. Defendants' conspiracy and their actions and omissions in furtherance thereof caused the direct and foreseeable losses alleged herein.

669. Defendants' misconduct alleged in this case is ongoing and persistent.

670. Because of Defendants' dissemination of false information and misleading information of opioid risks, benefits, and sustainability for chronic pain, and false and misleading

statements regarding compliance with laws concerning the distribution of opioids, Defendants are responsible for the costs of addressing the public health crisis that they created and they are liable and responsible under RICO for their conspiracy.[186]

671. Defendants conspired to create a public nuisance and to commit tortious conduct and are therefore jointly and severally liable for the damages flowing from the conspiracy.

672. Plaintiff has suffered monetary damages as aforesaid. As such Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants as well as attorney fees and costs, and pre- and post-judgment interest.

~~COUNT II~~

~~Violation of Racketeering Influenced and Corrupt Organizations Act (18 U.S.C. §§ 1961–1968)~~

673. ~~Plaintiff repeats, realleges, and incorporates by reference the preceding paragraphs of this Complaint, as if fully set forth herein.~~[187]

674. ~~This claim alleges violations of 18 U.S.C. §§ 1962(c) (d), and is an underlying unlawful act committed by Defendants through an unlawful or corrupt combination or agreement to engage in concerted action to perpetuate these unlawful acts.~~

675. ~~At all relevant times, Plaintiff was capable of holding legal or beneficial interest in property and so were each a "person" within the meaning of 18 U.S.C. §§ 1961(3), 1962(c).~~

[186] *See supra* n.3.

[187] *See supra* n.3., indicating Defendants are not now required to answer the allegations concerning Count II, Violation of Racketeering Influenced and Corrupt Organizations Act (18 U.S.C. §§ 1961-1968), which are contained within paragraphs 673 through 720) within the bellwether, Track 23. This RICO Count is severed from the bellwether proceeding and stayed. The strikethrough text utilized to plead this cause of action is utilized to represent that—while Plaintiff has asserted this RICO Count—the RICO Count is stayed and severed from the bellwether. For the avoidance of doubt, the strikethrough text is not an indication that Plaintiff is not asserting this RICO Count or has foregone or dismissed the RICO Count.

A. Structure of the Opioid Promotion Enterprise

676. **Name:** At all relevant times, there existed an "enterprise," within the meaning of 18 U.S.C. §§ 1961(4), 1962(c) – to wit, an association-in-fact comprised of each Defendant as well as other members – referred to herein as "The Opioid Promotion Enterprise."

677. **Continuity**: The activities of the Opioid Promotion Enterprise were continuous, beginning in the 1990s and continuing until at least within four years prior to the filing of this Complaint.

678. **Effect on Commerce**: The Opioid Promotion Enterprise was engaged in, and its activities affected, interstate or foreign commerce.

679. **Membership**: The Opioid Promotion Enterprise reflected several types of participants, not all of whom were complicit, and not all of whom are named as Defendants:

i. **The Manufacturing Associates and Associates**. The Manufacturing Associates (including unnamed co-conspirators Purdue, Endo, and Mallinckrodt) engaged in unlawful conduct to promote greater use of prescription opioids, engaged in unlawful conduct related to the distribution of opioids, and conspired with other members of the Opioid Promotion Enterprise.

ii. **Front Groups and KOLs**. The Manufacturing Associates used the Front Groups and KOLs to stoke demand for opioids by falsely creating the impression of independent, third-party, authoritative validation of the Manufacturing Associates' false claims.

iii. **Trade Associations.** Defendants participated in and used various trade associations, including the Pain Care Forum, the Healthcare Distribution Alliance, and the National Association of Chain Drug Stores as fora to develop and coordinate the unlawful activities of the Opioid Promotion Enterprise and to promote various aspects of the scheme.

iv. **Distributor Defendants.** The Defendants and Distributor Associates joined the Opioid Promotion Enterprise with full awareness and complicity and acted in concert with the Manufacturing Associates. The Distributor Associates and Defendants engaged in unlawful conduct to promote greater use of prescription opioids, engaged in

unlawful conduct related to the distribution of opioids, and conspired with other members of the Opioid Promotion Enterprise.

v. **National Retail Pharmacies.** In addition to their conduct as Distributor Defendants, Defendants engaged in unlawful conduct related to dispensing of prescription opioids and conspired with other members of the Opioid Promotion Enterprise.

vi. **Noramco.** Noramco engaged in unlawful conduct related to the production and importation of active pharmaceutical ingredients for prescription opioids and conspired with other members of the Opioid Promotion Enterprise to increase the sale of prescription opioids.

vii. **McKinsey.** McKinsey engaged in unlawful conduct related to the marketing and distribution of prescription opioids and conspired with other members of the Opioid Promotion Enterprise to increase the sale of prescription opioids.

viii. **Corrupt Physicians and Pharmacies, a/k/a Pill Mills.** These participants unlawfully prescribed and dispensed prescription opioids.

B. The Common Purpose and Scheme of the Opioid Promotion Enterprise

680. The purpose of the Opioid Promotion Enterprise was to increase the sale of prescription opioids, thereby increasing Defendants' revenues and profits. The members of the enterprise agreed to work towards this purpose by propagating falsehoods about the safety, risks, and benefits of opioids and about the way they are or should be distributed and dispensed, by unlawfully distributing and dispensing opioids, and by conspiring to do these things.

681. Knowing that prescription opioids were highly addictive as well as ineffective and unsafe for the treatment of chronic pain, Defendants formed the Opioid Promotion Enterprise and engaged in a scheme to increase their profits and sales through (1) repeated and systematic misrepresentations about the safety and efficacy of opioids for treating chronic pain and (2) ongoing disregard of their duties to identify, investigate, halt, and report diversion of prescription opioids, and to fulfill their obligations under the CSA for distribution and dispensing of prescription opioids.

682. ~~At all relevant times, Defendants conducted (managed) or participated, directly or indirectly, in the conduct (management) of the Opioid Promotion Enterprise, through a pattern of unlawful or otherwise prohibited activity. Defendants, with full knowledge and purpose, also conspired with members of the Opioid Promotion Enterprise, in violation of 18 U.S.C. § 1962(d), to violate § 1962(c).~~

683. ~~There was regular communication between Defendants, the Front Groups, the KOLs, and the Trade Associations in which information was shared, misrepresentations coordinated, and payments exchanged. This coordination, communication, and payment often required the use of the wires and mail given the geographic dispersal of the members of the Opioid Promotion Enterprise.~~

684. ~~As public scrutiny and media coverage revealed how opioids ravaged communities throughout the United States, Defendants, the Front Groups and KOLs did not challenge the Manufacturing Associates' misrepresentations, seek to correct their own previous misrepresentations, terminate their role in the Opioid Promotion Enterprise, or disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence.~~

685. ~~Defendants and the Manufacturing Associates could not have accomplished the purpose of the Opioid Promotion Enterprise without the assistance of the Front Groups and the KOLs, who were perceived as "neutral" even while spreading misrepresentations about opioids.~~

686. ~~The impact of the Opioid Promotion Enterprise is still in place, i.e., opioids continue to be prescribed and used for chronic pain, and the wave of opioid-dependent patients continues to consume Plaintiff's resources.~~

687. ~~Defendants, Front Groups, KOLs, and Trade Associations were all willing participants in the Opioid Promotion Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the enterprise's purpose.~~

~~C. Pattern of Racketeering Activity~~

688. ~~Members of the Opioid Promotion Enterprise engaged in multiple, repeated, and continuous criminal acts, including but not limited to:~~

a. ~~**Wire Fraud, 18 U.S.C. § 1343.** Members of the Opioid Promotion Enterprise, in violation of § 1343, transmitted communications electronically to designated persons to assert and/or coordinate false claims regarding the benefits, risks, sale, distribution, and dispensing of prescription opioids with the overall aim of increasing sales of prescription opioids and collecting the resulting profits.~~

b. ~~**Mail Fraud, 18 U.S.C. § 1341.** Members of the Opioid Promotion Enterprise, in violation of § 1341, transmitted communications by the mail to designated persons to assert and/or coordinate false claims regarding the benefits, risks, sale, distribution, and dispensing of prescription opioids with the overall aim of increasing sales of prescription opioids and collecting the resulting profits.~~

c. ~~**Obstruction of Official Proceedings, 18 U.S.C. § 1512(c).** Members of the Opioid Promotion Enterprise, in violation of § 1512(c), corruptly obstructed, influenced, and/or impeded one or more official proceedings and/or attempted to do so. These proceedings included hearings before congressional committees, administrative proceedings before the FDA and the DEA, and proceedings before United States courts.~~

d. ~~**Violations of the Controlled Substances Act, 21 U.S.C. § 801, *et seq.*** Members of the Opioid Promotion Enterprise, in violation of § 843(a)(4)(A), knowingly or intentionally failed to report suspicious orders of prescription opioids that they were required to report. Members of the Opioid Promotion Enterprise, in violation of §§ 821, 822(b), 841(a), and 21 C.F.R. § 1301.74, distributed prescription opioids without authorization by knowingly failing to design and operate a system to detect suspicious orders of prescription opioids. Members of the Opioid Promotion Enterprise, in violation of §§ 821, 822(b), 841(a), and 21 C.F.R. § 1301.71(a), distributed prescription opioids without authorization by knowingly failing to maintain effective controls against diversion of prescription opioids into other than legitimate medical, scientific, and industrial channels by, among other things, shipping suspicious orders of prescription opioids without dispelling the suspicion. Defendants , in violation of §§ 821, 822(b), and 841(a), knowingly dispensed prescription opioids without authorization by, among other things, failing to comply with the procedures mandated by 21 C.F.R. Part 1306. Members of the Opioid Promotion Enterprise, in violation of § 843(b), knowingly or intentionally~~

used a communication facility (including the mail and wires) to facilitate the commission of the above violations of the CSA. Each Defendant, in violation of § 846, willingly agreed with at least one other person to a plan to knowingly commit one or more of the above violations of the CSA.

e. **Violations of State Controlled Substances Laws.** Members of the Opioid Promotion Enterprise violated state-controlled substances laws that prohibit unauthorized dealing in controlled substances that are defined in section 102 of the Controlled Substances Act, including hydrocodone, oxycodone, and fentanyl.

689. Each Defendant used the mail and wires to participate in the operation or management of the affairs of the Opioid Promotion Enterprise, directly or indirectly, in one or more of the following ways:

a. Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about the risks and benefits of opioids, electronic and print advertisements about opioids, sales and promotional training materials about opioids, and CMEs and speaker presentations about opioids that understated the risks and overstated the benefits of long-term use;

b. Making inaccurate assertions that their promotion of prescription opioids had always been done in a manner that was safe and nonmisleading;

c. Selecting, cultivating, promoting, and paying KOLs, Front Groups, and Trade Associations;

d. Paying KOLs to serve as consultants or on the Manufacturing Associates' advisory boards, to serve on the advisory boards and in leadership positions of Front Groups, and to give talks or present CMEs;

e. Paying significant amounts of money to leaders and individuals associated with Front Groups;

f. Donating to Front Groups to support talks or CMEs;

g. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

h. Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

i. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters and the help of the Front Groups as publishers and supporters;

j. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the Manufacturing Associates, such as the elderly, and then funding that distribution;

k. Concealing their relationship to and control of Front Groups and KOLs;

l. Fraudulently claiming that they were complying with their duties to maintain effective controls against diversion, including duties to identify, investigate, halt shipment of, and report suspicious orders of opioids;

m. Fraudulently claiming that they were complying with their obligation to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;

n. Fraudulently claiming that they did not have the capability to identify suspicious orders of controlled substances;

o. Applying political and other pressure to halt prosecutions for failure to report suspicious orders of prescription opioids;

p. Lobbying for less stringent regulation of their marketing and distribution of pharmaceutical products.

q. Communicating with one another and with other members of the Opioid Promotion Enterprise via e-mail, telephone, and written communications regarding the management, operation, and/or participation in the enterprise and in the unlawful statement regarding the risks and benefits of prescription opioids;

r. Communicating with state agencies, federal and state courts, and private insurers regarding their misrepresentations regarding risks and benefits of using opioids for chronic pain;

s. Receiving monies through the mails and wires, including payments for prescription opioids;

t. Sending the prescription opioids themselves through the mails as well as the associated bills of lading, invoices, shipping records, reports, and correspondence; and

u. Sending documents intended to facilitate or control the dispensing of prescription opioids, including Defendants and the National Retail Pharmacies' nationwide policies and procedures that controlled the conduct of individual retail pharmacies.

690. For the Opioid Promotion Enterprise to work, each member had to agree to implement similar tactics regarding fraudulent promotion of the use and sale of prescription opioids. This conclusion is supported by the fact that Defendants each financed, supported, and

~~worked through the same KOLs, Front Groups, and Trade Associations and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines. Defendants specifically intended that further to their conspiracy, some conspirator would commit each element of the predicate acts complained of herein. Defendants intended that they and/or their co-conspirators, the unnamed associates would ship opioids in violation of the CSA in manners that were conducted by their coordinated failures to maintain effective controls against diversion of controlled substances, here opioids, including reviewing and stopping suspicious order distributions, and otherwise comply with the requirements of the CSA for distributors. Defendants also specifically intended that some conspirator intended and did in fact issue prescriptions for controlled substances (here, prescription opioids) not for legitimate medical purposes by a practitioner acting in the course of his or her professional purposes knowingly filled by a pharmacist.~~

691. ~~The Front Groups, KOLs, and Trade Associations also conducted and participated in the conduct of the Opioid Promotion Enterprise, directly or indirectly, by means of mail and wires in one or more of the following ways:~~

~~a. Making misrepresentations regarding opioids;~~

~~b. Distributing promotional and other materials that claimed that opioids could be safely used for chronic pain without risk (or with minimal risk) of OUD and dependency and that misrepresented the risk-benefit balance of using opioids for chronic pain;~~

~~c. Amplifying messages favorable to increased opioid use – and ultimately, the Defendants' financial interests;~~

~~d. Drafting and issuing guidelines and policies that minimized the risk of OUD, promoted opioids for chronic pain, and promoted policies and procedures for the distribution and dispensing of prescription opioids that were deliberately ineffective at preventing diversion; and~~

~~e. Concealing the connections among themselves and to Defendants.~~

692. ~~Defendants who participated in official proceedings corruptly obstructed, impeded, or influenced those proceedings in one or more of the following ways:~~

693. ~~Making misrepresentations regarding the safety or efficacy of prescription opioids;~~

694. ~~Making misrepresentations regarding their own actions to comply with controlled substances laws and otherwise prevent opioid diversion and misuse; and~~

695. ~~Soliciting the support of supposedly "neutral" witnesses or groups that Defendants actually financed and/or controlled to testify and/or submit comments in support of increased opioid use and looser regulations of opioid sales.~~

696. ~~Such proceedings included, but are not limited to:~~

697. ~~Congressional testimony, lobbying, and submission of materials to members of Congress in association with the Ensuring Patient Access and Effective Drug Enforcement Act, the Military Pain Act, the National Pain Policy Act;~~

698. ~~Congressional testimony seeking to modify the "80/20" that limited Noramco's access to the U.S. market;~~

699. ~~Congressional testimony by ADBC, McKesson, Cardinal, and H.D. Smith minimizing and/or denying their role in creating the opioid crisis;~~

700. ~~Submission of an amicus brief in *Cardinal Health v. Holder*;~~

701. ~~Testimony and submissions in connection with FDA administrative actions, including those surrounding the creation of the ER/LA opioid REMS; and~~

702. ~~Testimony and submissions in connection with DEA investigations and enforcement actions.~~

703. ~~Defendants conspired to and did violate their obligations under the CSA and its state equivalents. Under laws regulating controlled substances, Defendants are duty bound to~~

~~identify, report, and not ship suspicious orders of controlled substances. Defendants jointly agreed to and did, in fact, disregard their duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs in one or more of the following ways:~~

704. ~~Unlawfully distributing and/or dispensing prescription opioids;~~

705. ~~Furnishing false or fraudulent information in their reports about suspicious orders, and/or omitting material information from reports, records, and other documents required to be filed, including suspicious orders of prescription opioids;~~

706. ~~Refusing to comply with their obligations under the law to prevent diversion by, among other things, failing to halt and report suspicious orders of prescription opioids and creating policies and procedures that allowed suspicious prescriptions to be filled without adequate due diligence;~~

707. ~~Failing to report and halt CSA violations by other members of the Opioid Promotion Enterprise and, in some cases, actively facilitating other members' violations;~~

708. ~~Deceiving regulators, the public, and Plaintiff that Defendants were complying with their legal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market.~~

709. ~~By designing and deploying defective systems for identifying suspicious orders and/or prescriptions that could not lawfully be filled under the CSA and other drug control laws, Defendants deliberately closed their eyes to what would otherwise have been obvious – namely, that their customers were placing suspicious orders and/or presenting prescriptions that should not have been filled. The volume of prescription opioids that they distributed and/or dispensed implies~~

~~that failure to notice that some of the orders and/or prescriptions were ones that could not lawfully have been shipped and/or dispensed was deliberate.~~

710. ~~Because Defendants often communicated verbally when discussing their plans, this led to all adopt similar models for reporting suspicious orders (i.e., models that resulted in the commission of violations of controlled substance laws), the similarities allow an inference of tacit agreement regarding Defendants' compliance with controlled substance laws.~~

711. ~~The Pill Mills conducted and participated in the conduct of the Opioid Promotion Enterprise, directly or indirectly, by unlawfully prescribing and/or dispensing prescription opioids.~~

712. ~~The scheme devised and implemented by the members of the Opioid Promotion Enterprise amounted to a common course of conduct intended to increase sales of prescription opioids by encouraging the prescribing and use of opioids for chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.~~

713. ~~Each member of the Opioid Promotion Enterprise agreed, with knowledge and intent, to the overall objective of the enterprise and participated in the common course of conduct to commit unlawful acts for the purpose of increasing the sales of prescription opioids.~~

714. ~~The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.~~

715. ~~Defendants' conduct was not merely parallel. While certain Defendants engaged in similar conduct (e.g., various Manufacturing Associates made similar misrepresentations regarding the safety and efficacy of prescription opioids), they engaged in that conduct while communicating and coordinating with one another.~~

716. ~~The elements of these predicate acts occurred within the United States and/or the predicate acts violated U.S. statutes with extraterritorial reach.~~

~~D. Conspiracy~~

717. ~~Even if a Defendant did not personally commit a predicate act, each Defendant conspired with other members of the Opioid Promotion Enterprise in violation of 18 U.S.C. § 1962(d).~~

718. ~~Each Defendant, whether or not it personally committed a predicate act, agreed to participate in the Opioid Promotion Enterprise, with knowledge that at least one member of the enterprise intended to (and did) commit at least two predicate acts.~~

719. ~~For instance, each Defendant knew and intended that the Defendants would dispense prescription opioids in violation of the CSA. This knowledge and intent can be inferred because Defendants could not profit from prescription opioids unless they were actually dispensed.~~

~~E. Consequences~~

720. ~~By reason of the above-referenced violations of 18 U.S.C. § 1962(c) (d), Plaintiff was injured in its business or property within the meaning of 18 U.S.C. § 1964(c) and is entitled to assert this claim and to recover threefold the damages they sustained and the cost of the suit, including reasonable attorneys' fees, as well as such other appropriate relief as the Court may provide.~~

COUNT III

Nuisance

721. Plaintiff repeats, realleges, and incorporates by reference paragraphs 1 to 673 of this Complaint, as if fully set forth herein.

722. The nuisance is the over-saturation of opioids in the patient population of Plaintiff and in the geographic area served by Plaintiff for illegitimate purposes, as well as the adverse social, economic, and human health outcomes associated with widespread illegal opioid use.

723. All Defendants substantially participated in nuisance-causing activities.

724. Manufacturing Associates and CVS participated in nuisance-causing activities by, as described in Section III, through their marketing of opioids.

725. All Defendants participated in nuisance-causing activities by distributing and selling opioids, as described in Section III, and/or otherwise exacerbating the flood of opioids into Plaintiff's communities in ways that unreasonably interfere with the public health, welfare, and safety in Plaintiff's communities.

726. Additionally, all Defendants are jointly liable for the conduct of their co-conspirators as per the collective conduct allegations in Section III.

727. Defendants' nuisance-causing activities include selling or facilitating the sale and distribution of prescription opioids to the patients who seek treatment for all purposes (not merely overdoses) at the Plaintiff's Hospitals, as well as to other members of the communities in Kentucky.

728. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of controlled substances, and their failure to adequately design and operate a system to detect, halt and report suspicious orders of controlled substances.

729. Defendants' activities unreasonably interfere with the operational rights of Plaintiff. Defendants' interference with Plaintiff's rights is unreasonable because it:

a. Has harmed and will continue to harm the public health services of and public peace of Plaintiff;

b. Has harmed and will continue to harm the communities and neighborhoods which Plaintiff serves;

c. Is proscribed by statutes and regulation, including the CSA, pharmacy regulations, and the consumer protection statute;

d. Is of a continuing nature and it has produced long-lasting effects;

e. Defendants have reason to know their conduct has a significant effect upon Plaintiff; and

f. Has inflicted on Plaintiff substantial operational losses.

730. The nuisance undermines public health, quality of life, and safety. It has resulted in high rates of addiction, overdoses, dysfunction, and despair within families and entire communities. It has created a public health crisis.

731. The resources of Plaintiff are being unreasonably consumed in efforts to address the prescription drug abuse epidemic, thereby eliminating available resources needed in other health care areas.

732. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in facilitating widespread opioid addiction and failing to identify, halt, and report suspicious opioid transactions.

733. At all times, all Defendants possessed the right and ability to (a) tell the truth about their opioid products' effectiveness; (b) tell the truth from the onset about their opioid products' dangerous propensities; (c) control the nuisance causing outflow of opioids from pharmacy locations or other points of sale; and (d) the truth about their failures to comply with the CSA. Defendants and the unnamed associates had the power to shut off the supply of illicit opioids to Plaintiff and in the geographic area served by Plaintiff.

734. As a direct and proximate result of the nuisance, Plaintiff has suffered and sustained unusual and/or special injury and damage, differing from that sustained by the community at large, including sustained economic harm in the form of operational losses associated with treating OUD patients, and by being caused to spend money trying to remedy the harms caused by Defendants' nuisance-causing activity, including, but not limited to, screening patients, coordinating of care for patients both upon arrival and at the time of discharge, for the purpose of OUD patients having fewer visits of shorter duration. In short, Defendants created a mess, leaving it to Plaintiff and other hospitals to locate and direct resources for the cleanup. This is a classic nuisance.

735. As a result of Defendants' actions, Plaintiff has suffered a special injury, different from that suffered by the public at large by individual users and by governmental entities, namely that Plaintiff is required by law (EMTALA) to receive and treat OUD patients with more resources while sustaining operational losses as described, herein.

736. The effects of the nuisance can be abated over time, and the further occurrence of such harm and inconvenience can be prevented. All Defendants share in the responsibility for doing so.

737. Defendants should be required to pay for the resources, staff, equipment and strategic and clinical programming necessary for Plaintiff to mitigate further harm and abate the nuisance (and therefore the harm).

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff asks that the Court:

A. Enter judgment against Defendants, jointly and severally, and in favor of Plaintiff;

B. Award compensatory damages in an amount sufficient to fairly and completely compensate Plaintiff for all damages; treble damages; pre-judgment and post-judgment interest as provided by law and at the highest legal rate;

C. Award such equitable relief against Defendants as the Court should find

appropriate;

D. Award Plaintiff its cost of suit, including reasonable attorneys' fees as provided by law; and

E. Award such further and additional relief as the Court may deem just and proper under the circumstances.

XIII. JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Dated: April 30, 2025

Respectfully Submitted,

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